Menopause

Patient Management Guide

New Edition December 2025

The Consilient Health Menopause Patient Management Guide has been developed in conjunction with Dr Caoimhe Hartley and Dr Deirdre Lundy.

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Menopause

Patient Management Guide

This guide is based on recommendations supported by the **British Menopause Society** and the **International Menopause Society** (although many other excellent resources exist).[1, 2] **Menopause Hormone Therapy** or **MHT** is fast regaining its popularity in Ireland as one of the many ways we can help relieve some of the symptoms of the Menopause.

Use of **MHT** has a limited risk profile when compared to other types of oestrogen+progestogen medications (specifically the combined hormone pills, patch and ring). **MHT** medications contain physiological types of oestrogens, progestogens (+/- androgens) and usually contain very small doses. As with all medications, there are some risks so this flip chart hopes to provide support and reassurance to **MHT** advisors, prescribers and their patients.

We use the word women and female throughout this resource. Although we recognise that not everyone impacted by menopause identifies as a woman it is a fact that typical menopause research and data does not include transgender men or other gender diverse people.

Definitions and Abbreviations

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ABC

Definitions

Perimenopausal is the time leading up to a woman's final period. There may be variability in the menstrual cycle, vasomotor symtpomts, mood changes etc.. The typical age of onset is from 45 years onwards but some women experience symptoms earlier.
Early Menopause is defined as a menopause between 40 and 45 years and occurs in about 5% of women.
Premature Ovarian Insufficiency (POI) is when FSH levels measure in the postmenopausal range in a person under 40 years. It affects about 1% of women.

Abbreviations

AI Aromatase Inhibitor
BMI Body Mass Index
BMS British Menopause Society
BP Blood Pressure
BSO Bilateral Salpingo Oophorectomy
BV Bacterial Vaginosis
CHC Combined Hormonal Contraception
CVA Cerebral Vascular Attack
CVD Cardiovascular Disease
DEXA / DXA Dual-Energy X-ray Absorptiometry / Bone Density Scan
DHEA Dehydroepiandrosterone
DYDRG Dydrogesterone
FBC Full Blood Count
FSH Follicle Stimulating Hormone
GMS / GUSM Genito-urinary Syndrome of the Menopause. This is the new term for vulvo-vaginal atrophy
HBA1C HbA1c is known as glycated haemoglobin. It is made when the glucose (sugar) in your body sticks to your red blood cells. A high HbA1c level means you have too much glucose in your blood
HRT Hormone Replacement Therapy
IM MPA Intramuscular Medroxyprogesterone Acetate
IMS International Menopause Society
IUB Intrauterine Ball
IUS Intrauterine System
LMP Last Menstrual Period
LNG-IUS Levonorgestrel Releasing Intrauterine Device
MHT Menopause Hormone Therapy
MI Myocardial Infarction
MP Micronised Progesterone
NET Norethisterone
NKB/NK3R Neurokinin B/ neurokinin-3-receptor
OAB Overactive Bladder
PCOS Polycystic Ovarian Syndrome
PHQ-9 SCORE The Patient Health Questionnaire is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression[3]
PO Per oral
POI Premature Ovarian Insufficiency
POP Progestogen Only Pill
QOL Quality Of Life
SI Sexual Intercourse
SSRI Selective Serotonin Re-uptake Inhibitor
SNRI Serotonin Noradrenaline Re-uptake Inhibitor
TD Transdermal
TIA Transient Ischemic Attack
TSH Thyroid Stimulating Hormone
UTI Urinary Tract Infection
VMS Vasomotor Symptoms
VTE Venous Thromboembolism

Consultation Checklist: First Appointment[3,4]

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Diagnosis	• Last Menstrual Period • Assess bleeding pattern and impact on QOL, menopausal status • Consider measuring FSH to diagnose menopause in oligo/amenorrhoeic women aged< 45yrs. • Consider TSH / FBC / Ferritin / Coeliac screening etc. to rule out potential causes of symptoms.
Consider using symptom checker to assess: See Symptom Checker on consilienthealth.ie	• Physical symptoms • Genitourinary symptoms • Mood, Emotional symptoms
Past Medical History	• Current medications • Thyroid • Migraines • Hypertension • Diabetes • Endometriosis
Past Surgical History	Hysterectomy / Oopherectomy / Blood clots
Past Gynaecological History	NB. Consider Contraceptive requirement
Family History	• History of Breast Cancer/ Gynaecological Cancer • VTE
Smoking / Vaping Status / Alcohol intake screening	Number / Units per day
Screening	Cervical Smear / Mammogram / DEXA
Physical Exam	• Examine women where indicated by history • Blood Pressure / BMI Mandatory All else at discretion of clinician if indicated by complaints.
Other	In addition to using a symptom checker, as outlined above, where relevant consider using the PHQ9 Questionnaire to monitor severity of depression - available on the www.patient.info website[3]

Consultation Checklist: Patient Management

Consultation: Discussion re Management Options[4,5,6,33]

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Discuss options including; Lifestyle Interventions, Hormonal Options, Non-Hormonal Options, Contraceptive Options and Vaginal Moisturisers / Lubricants/Localised Oestrogen.

- Discuss potential risks and side effects including breast tenderness, headaches, bloating
- Explain that unscheduled or irregular bleeding can be common in the first 3-6 months after starting HRT[5]
- Combination HRT (oestrogen and progestogen) necessary for women with an intact uterus either as cyclical / sequential (for perimenopausal women) or continuous HRT (for postmenopausal women).
- Oestrogen alone can be prescribed for women who have had a hysterectomy. However combination HRT (oestrogen and progestogen) may be indicated for hysterectomised women with a history of endometriosis.

Risks: VTE and / or stroke risk increased with oral HRT compared to population risk. No increased risk associated with low dose transdermal preparations. Consider transdermal rather than oral oestrogen for menopausal women who are at increased risk of VTE, including those with a BMI over 30 kg/m^2/ women who have a history of migraine, smoking, diabetes etc. If personal Hx of VTE, refer to Menopause Speciality Clinic initially.

Breast Cancer: Baseline risk is dependent on individual factors including family history and lifestyle. According to the Women's Health Initiative clinical trials, HRT with oestrogen alone is associated with little or no change in breast cancer risk[38]. HRT with oestrogen and progestogen combined may be associated with an increased risk of breast cancer which is dependent on the type of progestogen used and duration of use[6]. According to the ICGP a review is recommended three months after commencing HRT and annually thereafter unless a sooner review is clinically indicated (e.g. side effects, inadequate effectiveness, adverse event).

Benefits: HRT is the most effective therapy for symptom control including vasomotor symptoms, joint and muscle pains, mood changes and sleep disturbances. It provides a reduction in cardiovascular disease for women aged < 60 and within 10 years of their LMP, and a significant reduction in osteoporosis.[4]

Consultation: Discussion re Management Options

Consultation Checklist: Review Appointment

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- Review response to treatment and any current symptoms
- Assess bleeding status/ pattern of bleeding
- Blood pressure
- Review risks and benefits of current management plan
- Review screening status
- Advise no arbitrary limits with regards to HRT use

Consultation Checklist: Review Appointment

Prescribing Guide – HRT Medicines[7,8,9,33,36,37]

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Oestrogen

Oral:

- **Estrofem** 2mg daily (estradiol)
- **Fematab** 1mg - 2mg daily (estradiol)
- **Premarin** 0.625mg PO daily (Conjugated estrogens)

Transdermal:

- **Divigel Transdermal Gel** The usual starting dose is 1.0mg oestradiol (1.0g gel) daily but the selection of the initial dose can be based on the severity of the patients' symptoms. Depending on the clinical response, the dosage can be readjusted after 2 to 3 cycles individually from 0.5g to 1.5g per day, corresponding to 0.5 to 1.5mg oestradiol per day.
- **Estradot Transdermal Patch** 25mcg/ 37.5mcg/ 50mcg/ 75mcg/ 100mcg estradiol per 24 hours. Patches should be applied to the abdomen below the waist
- **Evorel 50 Transdermal Patch** 50mcg estradiol per 24 hours.[36] Patches should be applied below the waist.
- **Lenzetto Transdermal Spray** 1.53mg estradiol 1-3 sprays daily to the forearm
- **Oestrogel Transdermal Gel** Starting dose 1-2 pumps (0.75mg - 1.5mg estradiol) once a day. Apply to the skin of the arms / shoulders or inner thigh daily.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all other medicines.

Prescribing Guide – HRT Medicines

Prescribing Guide – HRT Medicines[7,8,9,10,25,33,36,37*]

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Progestogen - doses outlined below are for women who are using ≤ 50mcg Oestrogen patch dose or equivalent

Bleed Producing/Sequential*:

- **Duphaston** Dydrogesterone: 10mg - 20mg PO daily x 12-14 days per cycle.
- **Utrogestan** Micronised Progesterone 100mg capsules. Recommended dose 200mg nocte PO for 12-14 days per cycle.[25]
- **Provera** Medroxyprogesterone Acetate: 10mg - 15mg PO x 12-14 days per cycle.

No Bleed/Continuous*:

- **Duphaston** Dydrogesterone: 10mg - 20mg PO daily.
- **Utrogestan** Micronised Progesterone 100mg capsules. Recommended dose 100mg nocte PO.[25]
- **Mirena** Intrauterine Device Levonorgestrel - provides 5 years of endometrial protection - 52mg IUCD with (in most cases) limited systemic side effects.
- **Provera** Medroxyprogesterone Acetate: 2.5 - 5.0mg PO daily.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Note: Guidance from the BMS states that "The dose of the progestogen should be proportionate to the dose of oestrogen" [33] All of these sequential progestogen doses are based on standard low dose oestrogen of 50 mcg or less. Over 50 mcg oestrogen will require additional progestogen.[25] See also new collaborative document from 2024: https://thebms.org.uk/publications/bms-guidelines/management-of-unscheduled-bleeding-on-hormone-replacement-therapy-hrt/

*Other progestogens, including norethisterone acetate/ other doses of micronised progesterone are also available as Exempt Medicinal Products, information on the supply of these medicines can be provided from the manufacturer. Further information on Exempt Medicinal Products can also be found on the HPRA website, www.hpra.ie

Prescribing Guide – HRT Medicines

Prescribing Guide – HRT Medicines[7,8,9,10,25,33,36,37*]

Consilient Health

Progestogen - doses outlined below are for women on higher doses of oestrogen

Bleed Producing / Sequential*:

Any 75-100mcg Oestrogen equivalent &

- **Utrogestan** Micronised Progesterone (100mg capsules): Recommended dose 300mg nocte PO, for 12 - 14 days per cycle.[25]
- **Duphaston** Dydrogesterone: 20mg for 12-14 days/month
- **Provera** Medroxyprogesterone Acetate: 10mg for 12-14 days/month
- **Mirena** Intrauterine Device Levonorgestrel: 5 years only

Non-Bleed / Continuous*:

Any 75- 100mcg Oestrogen equivalent &

- **Utrogestan** Micronised Progesterone (100mg capsules): 200mg nocte PO[25]
- **Provera** Medroxyprogesterone Acetate: 5-10mg/day
- **Duphaston** Dydrogesterone: 20mg daily
- **Mirena** Intrauterine Device Levonorgestrel: 5 years only

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Note: Guidance from the BMS states that "The dose of the progestogen should be proportionate to the dose of Oestrogen" [33] Over 50 mcg Oestrogen will require additional progestogen. [25]

*Other progestogens, including norethisterone acetate/ other doses of micronised progesterone are also available as Exempt Medicinal Products information on the supply of these medicines can be provided from the manufacturer. Further information on Exempt Medicinal Products can also be found on the HPRA website, www.HPRA.ie

Prescribing Guide – HRT Medicines

Prescribing Guide – HRT Medicines[7,8,9,33,36,37]

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Combination Products

Bleed Producing/Sequential:

- **Femoston** Estradiol 1mg/2mg only x 14 tabs followed by Estradiol 1mg/2mg and Dydrogesterone 10mg x 14 tabs
- **Novofem** Estradiol 1mg only x 16 tabs followed by Estradiol 1mg and Norethisterone acetate 1mg x 12 tabs
- **Trisequens** Estradiol 2mg only tabs x 12 days followed by Estradiol 2mg and Norethisterone acetate 1mg tabs x 10 days followed by Estradiol 1mg tabs x 6 days

No bleed/Continuous:

Oral:

- **Activelle** Estradiol 1mg and norethisterone acetate 0.5mg PO daily
- **Kliogest** Estradiol 2 mg and norethisterone acetate 1mg
- **Angeliq** Estradiol 1mg and 2mg drospirenone
- **Femoston Conti** Estradiol and dydrogesterone 0.5mg/2.5mg or 1mg/5mg

Tibolone: Synthetic steroid compound. Has oestrogenic/ progestogenic /weakly androgenic effects. Do not need to add progestogen for endometrial protection.

Transdermal Patch:

- **Evorel Conti** Estradiol 50mcg and Norethisterone acetate 170mcg/ 24 hours.[37] Patches should be applied below the waist.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all other medicines.

Prescribing Guide – HRT Medicines

Prescribing Guide: Non-HRT Options [17, 31]

1. Lifestyle/Physical/Psychological therapies and treatments

Cognitive Behavioural Therapy (CBT) which combines relaxation techniques, sleep hygiene and learning to take a positive healthy attitude to menopause is also recommended. It can be offered too as a treatment for anxiety related to menopause. CBT can have an impact on both vasomotor symptoms, perception & control.

Avoiding heat triggers - hot tea and coffee, spicy foods, alcohol might launch a flush. Other common triggers include smoking, stress, exercise, and many more.

Environmental adjustments - keeping your environment cool (especially in the bed at night), wearing light layered clothing, electric fans, using ice packs or cooling packs. There are also benefits to reducing alcohol and caffeine.

Smoking cessation - ask your GP to get involved in helping you reduce or stop smoking.

Acupuncture/ acupressure for menopause - is probably quite safe when done by a well-trained practitioner but sadly has not been shown to relieve menopause symptoms, meaning any improvement may be placebo.

Yoga for menopause - there is no robust scientific evidence to prove that yoga specifically helps with flushes / sweats / mood etc. Many people gain enormous relief and pleasure from yoga. It can be a nice form of exercise and we know gentle exercise is good for so many medical complaints.

Massage - there are no large-scale clinical trials specifically looking at massage for menopause symptoms and comparing it to other menopause treatment options.

Vaginal Lasers for GSM - There is emerging evidence for the use of LASER therapy- particularly cold, Erbium LASER treatment as opposed to warm, CO_2 LASER therapy in treatment of GUSM/GSM. They are available in Ireland but can be expensive and clinical evidence for their use is lacking. Further studies on the use of local vaginal LASER for GSM are required.
Prof Tom Hilliard et al stated that Vaginal Erbium Laser may be considered for Post Menopausal women with a history of breast cancer.

Vaginal Moisturisers and Lubricants - May help improve the symptoms of vaginal dryness and discomfort and should be recommended for use in addition to local vaginal oestrogen.

Prescribing Guide: Non-HRT Options [17, 31]

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Managing menopause symptoms without HRT - for some people, non HRT therapies and products are a better fit

Not everyone is going to want or need HRT and some have been advised to avoid HRT. Most women will cope with their menopause symptoms on their own without involving their GP, for some people, non HRT therapies and products are a better fit.

2. Food and dietary supplements

Vitamins & Minerals

A balanced healthy diet is the ideal way to maintain good health through the menopause. If you have to avoid certain foods and worry you are not taking in enough vitamins or minerals, then an inexpensive multivitamin is a good idea. In Ireland, some supplemental vitamin D is advised as we do not get enough ambient sunshine – especially in the winter.

Herbal Products[31]:

Black Cohosh - The BMS say that while some studies do show Black Cohosh can help relieve vasomotor flushes and sweats, it is also associated with side effects (such as constipation, stomach cramps, heart rhythm disorders, weight gain) but most importantly, it interferes with the breast cancer drug 'Tamoxifen' and so must not be used in people using that medicine.

St John's Wort - Classified as Prescription Only in Ireland. It has been shown to be effective for both menopausal flushing and low mood. It may impair the activity of other medications as it is a liver enzyme inducing drug. So people on certain cancer drugs, hormonal contraception, HRT, etc. need to avoid it. Women who are being treated for breast cancer with Tamoxifen must not take St John's Wort.

Ginseng - The BMS say Ginseng and Chinese herbal medicines have not been shown to improve hot flushes, anxiety or low mood.

Isoflavones - Found in legumes such as soybeans, chickpeas and tofu. The BMS says "Most studies evaluating effectiveness of phytoestrogens are of poor quality and were not shown to reduce hot flush frequency. Data on phytoestrogen safety and survival benefits in breast cancer patients are inconsistent and as they are known to have oestrogenic activities, isoflavones including Red Clover are not recommended for breast cancer survivors."

Wild yam, Red clover, Dong quai, Gingko, Sage, Maca, Pollen extract, Vitamin E, Evening primrose Oil: No evidence to show they help with menopausal symptoms.

3. Prescription Medications[1,31,32,33]

A. Selective Serotonin re-uptake inhibitors (SSRI) and the Serotonin Noradrenaline re-uptake inhibitor/Selective Serotonin re-uptake inhibitors (SSRI-SNRI) are normally used for depression and anxiety but in the USA, the FDA approved Paroxetine for menopausal hot flushes. Venlafaxine 37.5mg titrated up to 150mg per day, Paroxetine 10mg daily or Citalopram 10mg-30mg are the most effective according to the BMS consensus statement [31]. Fluoxetine has evidence of efficacy and lower incidence of side effects. Sertraline seems least effective. Escitalopram improves flushes and has significant benefits and improvement in wellbeing but some side effects. Side effects include dry mouth, nausea, constipation - dose related. Reduced libido is a class effect.

Some SSRIs inhibit cytochrome P450 activity which is involved in Tamoxifen metabolism so most guidelines recommend that SSRIs such as Fluoxetine and Paroxetine must not be prescribed concomitantly with Tamoxifen. So, as **Paroxetine 10mg** is the SSRI with the best evidence for efficacy (although 20 mg may be used if an antidepressant effect is also required), it is the SSRI of choice for patients not taking Tamoxifen. **Venlafaxine 75mg is the preferred treatment for breast cancer survivors taking Tamoxifen.**

B. Gabapentin is an anti-epileptic medicine but 300mg daily increasing to 300mg TDS OR Pregabalin 75-150mg BD shows significant improvement in hot flushes as compared with placebo according to the BMS. It is recommended to start patients on a sub therapeutic dose of 100mg to avoid side effects. Dose dependent side effects may affect compliance, the most common side effects being somnolence, dizziness, weight gain and dry mouth. Gabapentin may be as effective as Venlafaxine. Pregabalin is licenced for depression.

C. Oxybutynin is an anticholinergic medication for urinary incontinence/ overactive bladder when taken 2.5 mg or 5 mg BD appears to be effective in the treatment of hot flushes in menopause including breast cancer survivors – trials are underway in the USA. Possible side effects include dry mouth or eyes, headache, dizziness, vertigo, GI upset, dry eyes.

Note: It is not recommended to use the above medications in conjunction with one another

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

D. Neurokinin receptor antagonists demonstrate a rapid effect on VMS in many users. There are two medications currently being assessed for use in people being treated for breast cancer; Fezolinetant is a neurokinin 3 receptor antagonist while Elinzanetant is the first dual neurokinin-1 and 3 (NK-1 and 3). Fezolinetant is already available in the ROI but has not yet been approved for use in people treated for breast cancer. Elinzanetant is currently the subject of the Oasis 4 trial[32]. Recent data has shown significantly reduced vasomotor symptoms, improved sleep, and enhanced quality of life for women undergoing endocrine therapy for HR-positive breast cancer.

E. Clonidine: An adrenergic receptor agonist licensed in Ireland for the treatment of hypertension and menopause symptom control (hot flushes). Dose is 25mcg BD for 2 weeks, increased up to a maximum of 50mcg TID. One study showed significant reduction in the numbers of flushes + improved QoL compared with placebo in breast cancer survivors using 100mcg daily. Side effects of clonidine are dose related- at higher doses it causes sleep disturbance in >50 % of users. It must be withdrawn gradually as abrupt cessation can cause rebound hypertension. Clonidine obviously may not be suitable for patients with a baseline low blood pressure.

Compounded Bioidentical and Regulated Bioidentical Hormone Replacement Therapy[41]

These are hormone-containing pellets, creams or pessaries that are produced in private laboratories.

Compounded Bioidentical Hormone Replacement Therapy (cBHRT): Precise duplicates of human hormones which are produced by specialist pharmacies and do not follow the same regulatory pathway as conventional rBHRT.

Regulated Bioidentical Hormone Replacement Therapy (rBHRT): Precise duplicates of human hormones developed in a conventional way by the pharmaceutical industry and authorised by the regulators. [41]

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Treatment of Genitourinary Syndrome of the Menopause[11,12,13,14,15]

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Symptoms linked to declining systemic oestrogen levels, oestrogen receptor numbers and pelvic floor vasculature include- Thinning of both muscularity and epithelium (with an increase in fat deposition) resulting in:

- Altered pH with an increased potential for BV and other infections
- Traumatic Bleeding after SI or PV exams
- Vaginal dryness
- Vaginal burning & irritation
- Sexual symptoms such as lack of lubrication & Dyspareunia
- Urinary symptoms such as: Urgency, Frequency, Dysuria & recurrent UTIs.

First Line Treatments - Non Rx Medical Therapies

Most Menopause societies suggest patients should at least try non Rx medical therapies such as:

- Vaginal moisturisers which maintain vaginal hydration, long-term relief of vaginal dryness, decreased pH to premenopausal levels but – these do not improve epithelium (examples include- Replens, Regelle, Multi-gyn, Yes, etc)
- Vaginal lubricants which provide a temporary moistened vaginal epithelium. May be water, silicone or oil based (KY, Sylk, Yes, etc)
- Herbal remedies (soy, black cohosh, etc) have not been shown effective over placebo.[15]

When these are not adequate, Prescription GSM remedies are recommended.

Treatment of Genitourinary Syndrome of the Menopause

Treatment of Genitourinary Syndrome of the Menopause [7,11,12,13,14,15,36,37]

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Second Line Treatments - Local Vaginal Oestrogen

Symptoms usually respond very well to local vaginal oestrogen containing products. These generally do not enter the systemic circulation in any meaningful way and can be offered to almost all patients including patients for whom systemic HRT is contraindicated e.g. patients who have been diagnosed with breast cancer. There are some considerations though.

These include-

- Local Oestrogen will thicken the epithelium, decrease dryness, return vaginal pH to normal and improve microflora with fewer UTI and decreased OAB symptoms.
- Systemic oestrogen (HRT) may also help GSM patients, but they will often need both systemic & local therapy although there may be adherence issues; studies suggest just 50-70% take as recommended.
- Dosing in MIMS is not aligned with Menopause society guidelines – and 4-6 months to see full results so perseverance is needed.
- Side effects can include local irritation – this may be due to a sensitivity to the hormone or the excipients but is often because the damaged vulvo vaginal tissues are acutely sensitive to any and all products, should ease with continued use.
- Provides virtually no systemic effect apart from a brief rise when applied to an atrophic vagina – so don't stop/start treatment. Refer to oncology or an accredited menopause specialist for people on Aromatase Inhibitors.
- No impact on endometrium, opposing progestogen not required.
- Vaginal oestrogens are safe for the majority of women diagnosed with gynaecological malignancies and other serious co-morbidities including those for whom systemic HRT is contra-indicated (BGCS-BMS- Guidelines on Mgmt of Menopausal Symptoms after Gynaecological Cancer, Aug 2024).

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Treatment of Genitourinary Syndrome of the Menopause

Treatment of Genitourinary Syndrome of the Menopause [7,11,12,13,14,15,36,37]

Consilient Health

Treatments licensed for post-menopausal patients (Also useful for Premature Ovarian Insufficiency, Early Menopause and Perimenopause).

Blissel, Vagifem, Vagirux and Ovestin are contra-indicated in patients with breast cancer or gynaecological malignancies.
Seek Specialist Advice for these cases.

Blissel[42]	1g vaginal gel contains 50 micrograms Estriol.	Treatment of symptoms of vaginal atrophy due to oestrogen deficiency in postmenopausal women.	Initial treatment: One applicator-dose of vaginal gel per day for three weeks. Maintenance treatment One applicator dose (1g) of vaginal gel twice a week.	Vaginal Gel with Applicator
Ovestin	1g vaginal cream containing 1mg Estriol	Treatment of symptoms of vaginal atrophy due to oestrogen deficiency in post-menopausal women.	Initial Dose: One application (0.5g) daily for up to four weeks, followed by a gradual reduction. Maintenance dosage: One application twice a week	Vaginal cream with applicator
Vagifem	Oestrogen / Estradiol 10mcg	Vaginal atrophy due to oestrogen deficiency in post-menopausal women.	Initial Dose: One daily for two weeks Maintenance Dose: One twice a week	Vaginal Tablet (with individual applicators)
Vagirux	Oestrogen / Estradiol 10mcg	Treatment of vaginal atrophy due to oestrogen deficiency in post-menopausal women.	Initial dose: One daily for two weeks Maintenance dose: One twice a week	Vaginal Tablet (with a single reusable applicator)

Advice given is based on the experience of practitioners working in this area. Advice for Blissel is as per SPC. Please refer to the relevant SPC for all other medicines.

Treatment of Genitourinary Syndrome of the Menopause[10,36,37,39]

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Non-Oestrogen Prescription GSM therapies[10]

Prasterone (A DHEA cream approved in the USA for use in Non Oestrogen Receptor Positive Breast Cancer Patients with vaginal symptoms after breast cancer.) and **Ospemifene** (An Oral GSM medicine) are available as Exempt Medicinal Products, information on the supply of these medicines can be provided from the manufacturer. Further information on Exempt Medicinal Products can also be found on the HPRA website, www.HPRA.ie [10]

Non-Medical GSM therapies

1. **Fractional CO_2 delivered by apparatus**: One course of laser treatment includes two or three laser sessions at an interval of approximately 4 ± 1 weeks[39]. Annual maintenance is needed. The heat increases blood flow, collagen production & vaginal epithelial regrowth. No need for LA nor recovery time but local burning not uncommon. So this has mostly been replaced by Erbium laser treatment.

2. **Erbium Laser Rejuvenation** with brand names such as "Fotona Smooth" & "IntimaLase" are alternative LASER therapies to fractional CO_2. They are associated with less risk of local burning as erbium is a cold LASER.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Treatment of Genitourinary Syndrome of the Menopause

Testosterone[16,17,18]

Note: Testosterone is currently not licenced in Ireland for use in women in the treatment of menopause.

Testosterone is an important female hormone and is primarily produced by the ovaries and the adrenal glands.

Testosterone concentrations fall during the reproductive years. Loss of testosterone is particularly profound after early surgical and medical menopause and premature ovarian insufficiency when testosterone production decreases by more than 50%.

There is no cut-off blood level which can differentiate women with or without sexual dysfunction.

Indications:

- The only evidence-based indication for the use of testosterone in women is for the treatment of postmenopausal women who have been diagnosed as having hypoactive sexual desire disorder (HSDD).[16]
- Testosterone therapy in doses that approximate physiological levels for premenopausal women may exert a benefit on sexual function.[17]

What to prescribe:

- It is not recommended to prescribe any testosterone preparation that results in supraphysiologic concentrations of testosterone.
- With any prescription of testosterone, levels should be maintained in the normal female range.

From the BMS:

Compounded bioidentical testosterone preparations are not recommended by the regulatory authorities or the menopause societies.

Direct assays for the measurement of total and free testosterone are highly unreliable in the female range and are technically difficult.

Baseline total testosterone concentration should be measured before commencement, with a repeat level 6-12 weeks after treatment initiation. Patients should be monitored with a serum total testosterone level +/- free androgen index every 6 months. If no benefit is achieved after 6 months, treatment should be stopped.

Also see troubleshooting section re. testosterone related side effects

Troubleshooting: Oestrogen Risk[1,6,9,11,19,36,37]

VTE "the risk of venous thromboembolism (VTE) is increased by use of an oral oestrogen containing HRT product compared with baseline population risk, the risk associated with transdermal HRT given at standard therapeutic doses is no greater than baseline population risk". NICE

VTE Side Effects

ACTION

- Advise patients that there is 2-4x increased risk of VTE when starting oral oestrogen HRT.
- Risk of VTE with oral HRT use is highest in the first year.
- Advise patients that there is no increased risk with transdermal oestrogen when used in standard doses.
- HRT is not contraindicated, but a non-oral route is preferred in patients at higher risk of VTE such as: patients over 60 years, patients with a BMI > 30, patients with a personal history of VTE, patients with a strong family history of VTE, patients undergoing immobilisation or surgery etc.
- Norpregnane derivative progestogens (Nomegestrol and Norethisterone*) and particularly Medroxy Progesterone Acetate (Provera) are not recommended in patients with increased VTE potential.
  Prescribers should consider micronised progesterone, dydrogesterone or a levonogestrel intrauterine device for women at high risk of VTE
  *This is based on studies using oral norethisterone in the hormonal contraceptive pill as opposed to transdermal norethisterone. Available evidence from studies of the contraceptive pill suggests that transdermal administration may have a lower risk[19].

For patients with a personal history of VTE, HRT use should be discussed with their Haematologist and a prescriber with Menopause training. Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Troubleshooting: Oestrogen Risk[1,6,19,36,37 *]

Cardiovascular Disease "the presence of cardiovascular risk factors is not a contraindication to HRT as long as they are optimally managed." NICE

"The risk of developing cardiovascular disease is not increased by use of HRT when started in women aged under 60 years." NICE
"Evidence from the Cochrane data-analysis as well as the long-term follow-up data from the WHI showed no increase in cardiovascular events, cardiovascular mortality or all cause mortality in women who initiated HRT more than 10 years after the menopause"- BMS consensus statement 2024.

Cardiovascular Disease Side Effects

Patients with history of CVD should be referred to Complex Menopause Clinic.

ACTION

There is no reliable evidence linking the use of HRT to cardiovascular disease in women under 65 years. HRT can be offered to women with cardiovascular risk factors once those risks have been optimally managed.

Advise patients that many forms of HRT have a beneficial effect on lipids, vascular function, and sugar metabolism.

Data supports the concept of primary prevention of coronary vascular disease and CVD mortality when HRT is started in women under 60 years of age and within 10 years of their final period.

For patients with established CVD: HRT use should be discussed with their Cardiologist / Prescriber with Menopause training. HRT has been generally contraindicated but more recent data suggests that in women with a past history of MI who are being well managed and are stable, the cautious use of low dose transdermal oestrogen (<50 mcg) and micronised progesterone is acceptable.

The BMS experts have also advised members that peripheral vascular disease is only a special caution for HRT - not an absolute contraindication- but obviously avoid PO routes.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Smoking Cessation and Cardiovascular Disease Risk reduction

Consilient Health

SMOKING AND MENOPAUSE

Smoking is associated with increased risk of:

- Earlier onset menopause[1]
- Worsening vasomotor symptoms (e.g. hot flushes, night sweats)[1]
- Lower oestrogen levels and reduced response to Menopausal Hormone Therapy (MHT)[2]
- Developing osteoporosis and cardiovascular (CV) disease[1]

Quitting smoking is one of the most effective modifiable lifestyle changes to improve menopause and long term health outcomes.

Practical Intervention

ACTION Use the 3As (Ask, Advise & Act) brief smoking intervention approach:

ASK	• Ask and record smoking status at every visit • Identify readiness to quit
ADVISE	• Advise on the benefits of stopping (e.g. CV risk, MHT effectiveness, fracture risk) • Be clear, personalized, and encouraging
ACT	• Offer support • Write a script for smoking cessation pharmacotherapy (cytisinicline, bupropion or varenicline) Note: Not all options GMS reimbursed • Book a follow-up or review

1. British Menopause Society; What is menopause? Available at: https://thebms.org.uk/wp-content/uploads/2023/08/17-BMS-TfC-What-is-the-menopause-AUGUST2023-A.pdf (Accessed: July 2025) **2.** British Menopause Society (BMS), 2016. The 2016 BMS & WHC recommendations on hormone replacement therapy in menopausal women. Post Reproductive Health, 22(4), pp.165-183. Available at: https://journals.sagepub.com/doi/10.1177/2053369116680501 (Accessed July 2025)

Smoking Cessation and Cardiovascular Disease Risk reduction

Consilient Health

Smoking cessation pharmacotherapies can double or even triple the chances of quitting smoking compared to willpower alone, with evidence supporting cytisinicline, varenicline and bupropion as effective, well-tolerated, nicotine-free options[1]. These treatments are especially relevant for midlife women where cardiovascular risk and menopausal symptoms make cessation more critical and more complex. "Advise people that a combination of behavioural support and pharmacotherapy is the most effective way to stop smoking." NICE Guideline NG209[2]

Medicine	Mechanism	Typical Dose	Duration
Cytisinicline (Citidaron®)[3]	Partial agonist at nicotinic α4β2 receptors	Day 1–3: 1 tablet q2h (max 6/day) tapering to 1–2/day by Day 21.	25 days
Bupropion (Zyban®)[4]	NDRI – reduces cravings and withdrawal	150 mg OD x6 days, then 150 mg BD for remaining duration.	7–12 weeks
Varenicline (generic)[5]	Partial agonist at nicotinic α4β2 receptors	0.5 mg OD for 3 days, then 0.5 mg BD for 4 days, then 1 mg BD for remaining duration.	12 weeks

Clinical Considerations for Perimenopausal and Postmenopausal Women

- **Mood:** bupropion may improve depressive symptoms, but caution in patients with seizure history[4]
- **Weight:** increased appetite or weight gain have been reported in patients attempting to stop smoking
- **Bone Health:** quitting reduces fracture risk and supports bone density[6]
- **MHT Compatibility:** pharmacotherapy may improve MHT effectiveness by stabilising hormone levels[7]

References: 1. Cahill K et al. Pharmacological interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database Syst Rev. 2013(5):CD009329. **2.** National Institute for Health and Care Excellence (NICE). NG209: Tobacco: preventing uptake, promoting quitting and treating dependence. 2021. Available at: https://www.nice.org.uk/guidance/ng209/chapter/Treating-tobacco-dependence [Accessed: July 2025] **3.** Citidaron (cytisinicline) 1.5 mg film-coated tablets, SPC. Health Products Regulatory Authority (HPRA), Ireland. Available at: https://www.hpra.ie [Accessed: July 2025] **4.** Zyban (bupropion SR) SPC. HPRA, www.hpra.ie. [Accessed: July 2025] **5.** Varenicline Teva SPC. HPRA, www.hpra.ie. [Accessed: July 2025] **6.** Ward KD, Klesges RC. A meta-analysis of the effects of cigarette smoking on bone mineral density. Calcif Tissue Int. 2001;68(5):259–270. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC5352985/ (Accessed: July 2025) **7.** British Menopause Society (BMS), 2016. The 2016 BMS & WHC recommendations on hormone replacement therapy in menopausal women. Post Reproductive Health, 22(4), pp.165-183. Available at: https://journals.sagepub.com/doi/10.1177/2053369116680501 (Accessed July 2025)

Menopause and Obesity

Consilient Health

Understanding Menopause and Obesity

Why Does Weight Gain Occur Around Menopause?

- Hormonal Changes: Declining oestrogen levels during menopause shift fat distribution from hips and thighs to the abdomen, increasing visceral adiposity even without significant weight change. [1–3]
- Metabolic Slowdown: Ageing reduces resting energy expenditure, contributing to weight gain. [3]
- Sleep Disturbance & Mood Changes: Hot flushes, insomnia, and mood symptoms during menopause can drive emotional eating and reduced physical activity. [4]
- Insulin Resistance: Increases post-menopause, heightening risk for weight gain and type 2 diabetes. [5]
- Loss of Muscle Mass: Menopause accelerates sarcopenia, reducing basal metabolic rate and promoting fat gain. [3]

Impact: Obesity in post-menopausal women is linked to higher rates of cardiovascular disease, type 2 diabetes, osteoarthritis, and hormone-related cancers, especially breast and endometrial cancer. [2,6]

Model of Care Principles Relevant to Menopausal Women with Obesity (HSE, 2021)

The HSE's Model of Care for the Management of Overweight and Obesity [7] outlines critical strategies relevant to this cohort:

- Person-Centred Care: Weight management discussions should be respectful, non-judgemental, and tailored to menopause-specific factors.
- Early Intervention: Midlife is an opportune moment for intervention, before substantial weight gain occurs.
- Integrated Services: Access to multidisciplinary teams (MDTs) including dietitians, psychologists, physiotherapists, and obesity medicine specialists.
- Holistic Focus: Emphasis on improving health outcomes beyond weight loss alone (e.g. metabolic health, mobility, quality of life)

References: 1. Davis SR et al. "Understanding weight gain at menopause" Climacteric, 15:5, 419-429, DOI: 10.3109/13697137.2012.707385 **2.** Lovejoy JC. Weight gain in women at midlife: the influence of menopause. Obes Manag. 2009;5(2):52–56 **3.** Neves e Castro et al. "EMAS position statement: menopause and metabolic syndrome." Maturitas. 2012;72(2):145–150. **4.** North American Menopause Society (NAMS). Menopause Practice: A Clinician's Guide. 2022. **5.** Carr MC. The emergence of the metabolic syndrome with menopause. J Clin Endocrinol Metab. 2003;88(6):2404–2411. **6.** Collaborative Group on Hormonal Factors in Breast Cancer. Menarche, menopause, and breast cancer risk. Lancet Oncol. 2012;13(11):1141–1151. https://pmc.ncbi.nlm.nih.gov/articles/PMC3488186/, accessed July 2025. **7.** Health Service Executive (HSE). Model of Care for the Management of Overweight and Obesity. 2021.

MYS-0428-001 07/25, IE-MYS-202(1), Date of preparation: September 2025

Menopause and Obesity

Obesity Care and Management

The HSE endorses the 5 A's framework for structured, respectful obesity care. [7,8] The "5 A's" in Obesity Canada's framework for obesity management represent a step-by-step approach to guide healthcare professionals in addressing obesity with patients. These steps are: Ask, Assess, Advise, Agree, and Assist. This framework is designed to be a practical tool for healthcare providers, especially those in primary care, to initiate conversations about weight management and encourage behaviour change.

The 5 A's in Obesity Management	
Ask	• Ask permission to discuss weight in a sensitive way
Assess	• BMI / Edmonton Obesity Stage • Waist circumference, comorbidities, lifestyle, menopause symptoms • Root Causes • Complications
Advise	• Provide personalised information on the health benefits of modest weight loss (5–10%) • Long term strategies • Treatments
Agree	• Collaboratively set realistic goals and expectations • Establish SMART Goals and a Personalised Plan
Assist	• Education / resources, tools and follow up support • Identify Barriers • Follow up

References: 7. Health Service Executive (HSE). Model of Care for the Management of Overweight and Obesity. 2021. **8.** Canadian Obesity Network. 5As of Obesity Management. 2015

Menopause and Obesity

Consilient Health

Treatment Options for Obesity

Lifestyle Interventions

- **Energy Deficit:** Typically, a reduction of ~500–600 kcal/day.
- **Resistance Training:** Essential to preserve lean mass and mitigate sarcopenia.
- **Behavioural Support:** Sleep hygiene, stress management, and psychological support are crucial in menopause. [4,7]

Pharmacological Treatment Options		
Xenical® [9]	orlistat	120mg capsule
Mysimba® [10]	naltrexone and bupropion	8mg/90mg prolonged release tablet
Saxenda® [11]	liraglutide	6mg/ml solution for injection in pre-filled pen
Mounjaro® [12]	tirzepitide	2.5mg, 5mg, 7.5mg, 10mg 12.5mg and 15mg solution for injection in pre-filled pen or vial or kwikpen (prefilled pen)
Wegovy® [13]	semaglutide	0.25mg, 0.5mg, 1mg, 1.7mg and 2.4mg Flextouch solution for injection in pre-filled pen

- Please refer to the relevant SPC for all medicines. [9-13]
- Pharmacotherapy complements—not replaces—lifestyle intervention. [7,14]

Bariatric Surgery

- Suitable for severe obesity (BMI ≥40, or ≥35 with comorbidities) if other methods have failed. [7]
- Shown to improve cardiovascular, metabolic, and quality-of-life outcomes in post-menopausal women. [15]

References: 4. North American Menopause Society (NAMS). Menopause Practice: A Clinician's Guide. 2022. **7.** Health Service Executive (HSE). Model of Care for the Management of Overweight and Obesity. 2021. **9.** Xenical Summary of product characteristics available on hpra.ie **10.** Mysimba Summary of product characteristics available on medicines.ie **11.** Saxenda Summary of product Characteristics available on medicines.ie **12.** Mounjaro Summary of product characteristics available on medicines.ie **13.** Wegovy Summary of product characteristics available on medicines.ie **14.** NICE Guideline NG246. Obesity and Obesity Management. 2025, https://www.nice.org.uk/guidance/ng246, accessed July 2025 **15.** Sjöström L et al. Effects of bariatric surgery on mortality in Swedish Obese Subjects. N Engl J Med. 2007;357(8):741–752.

Troubleshooting: Oestrogen Risk[1,6,19,20,36,37 *]

STROKE

Stroke "the use of oral (but not transdermal) oestrogen is associated with a small increase in the risk of stroke but the baseline risk for women under 60 years is low." NICE

"HRT should not be recommended for the primary or secondary prevention of stroke, low dose (50mcg/day) TD oestrogen was not linked to an increased risk of Stroke, in patients under 60 who had been prescribed HRT. Higher dose TD oestrogen and oral oestrogen HRT were associated with an increased risk of stroke so exercise caution when prescribing for people with Stroke risk including patients over 60 years of age.

Progesterone type may have an impact on the risk of ischemic stroke. A French study showed a link between ischemic stroke and the use of HRT with norpregnane derivative progestogens (Norethisterone and Norgestrel) but not with the use of micronised progesterone (Utrogestan) or dydrogesterone (Duphaston)[20].

Stroke side effects

ACTION

- Advise patients that the use of low dose (50mcg/day) TD oestrogen was not linked to an increased risk of Stroke, but higher dose TD HRT and oral HRT may increase stroke risk- particularly ischemic stroke (with no effect on haemorrhagic stroke).
- Advise patients that the use of Micronised progesterone and Dydrogesterone are preferred for people with risk factors for stroke. People with stroke risk factors should have their modifiable risks managed before commencing HRT.
- Patients with a past history of stroke are generally advised to avoid HRT (particularly oral oestrogen products) or to discuss options with a menopause specialist.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Troubleshooting: Oestrogen Risk*[6,19,21-24,28,33,40]

Consilient Health

General Comments

Breast cancer The most commonly occuring female cancer in Ireland. One in nine women will develop breast cancer in their lifetime.[40]

- Breast cancer prognosis continues to improve.
- Several factors influence breast cancer risk including age, family history, parity, BMI, smoking, alcohol consumption etc.

Hormone Replacement Therapy

- Current evidence suggests that Oestrogen-only therapy is associated with little or no increase in the risk of breast cancer.[38]
- There is an increased risk of breast cancer with combined HRT which is duration dependent. Risk varies depending on the type of progestogen used.[6,19] The overall impact on risk with combination therapy is small in statistical terms when compared with modifiable lifestyle factors including alcohol. The chart on the next page can be useful when explaining the risk to a patient.
- For the majority of women, benefits of HRT in the short-term (up to five years) for symptom relief will exceed potential harm with overall reductions in all-cause mortality.
- Large observational data suggests that micronised progesterone and dydrogesterone are likely to be associated with a lower risk of invasive breast cancer when compared to other progestogens.
- There is no difference in breast cancer risk with oral versus transdermal oestrogen.
- Increasing doses of oestrogen do not appear to confer higher risk.[21]
- Mammogram and breast cancer screening can be continued as per local guidelines.
- There is no need for more frequent screening or to stop HRT prior to mammogram screening.

In women with a familial risk or high-risk benign breast condition, HRT exposure has not been shown to have an additive effect on the risk of diagnosis. These patients should be referred to a menopause specialist to discuss their management options.

Carriers of the BRCA1 and BRCA 2 gene mutation who have had risk-reducing bilateral salpingo-oopherectomy can be given HRT for symptom control and to reduce their risk of osteoporosis and cardiovascular disease, until the until the average age of menopause (51 years). A meta-analysis and recent systemic review on this showed no increase in the risk of breast cancer in women with BRCA mutations using HRT after BSO.[22,23]

*** Note: A history of breast cancer is a contraindication to systemic HRT - refer to a menopause specialist and oncologist / breast cancer team for advice.[33]**

Understanding the Risks of Breast Cancer[24]

Consilient Health

A comparison of lifestyle risk factors versus Hormone Replacement Therapy (HRT) treatment.

Difference in breast cancer incidence per 1,000 women aged 50-59.
Approximate number of women developing breast cancer over the next five years.

23 cases of breast cancer diagnosed in the UK general population

An additional four cases in women on combined hormone replacement therapy (HRT)

Four fewer cases in women on oestrogen only Hormone Replacement Therapy (HRT)

An additional four cases in women on combined hormonal contraceptives (the pill)

An additional five cases in women who drink 2 or more units of alcohol per day

An additional three cases in women who are current smokers

An additional 24 cases in women who are overweight or obese (BMI equal or greater than 30)

Seven fewer cases in women who take at least 2½ hours moderate exercise per week

Adapted from BMS Understanding Risks of Breast Cancer Tool.[24]

Troubleshooting: Minor Oestrogen Related Side Effects [36,37]

Minor Oestrogen related side effects

Breast tenderness/ Nipple sensitivity, Leg cramps, Nausea/ Indigestion, Bloating, Headaches, Irritability and Depression, Irregular bleeding or spotting (can occur during the first 4-6 months of starting HRT)

ACTION

Management Options:

1. Existing Patients: Reduce Oestrogen Dose. **New Patients:** If your patient is already sensitive to oestrogen, titrate up from a very low dose (25mcg patch, 1mg tablet, 1 spray or 1 pump of TD) until they can tolerate the hormone.

2. Delivering the oestrogen in pulses rather than sustained release- patches deliver oestrogen in a continuous feed over 3-4 days and this may have an impact on side effects and tolerance. If a patient is willing, change to a single daily application of oestrogen; the dose to be decided by the patient, until they adjust.

3. Change the delivery route (assuming an alternative delivery route is not contraindicated).

4. Prescribe a different Oestrogen Medicine

Note: It may take 3 to 4 months before tolerance is developed.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Troubleshooting: Progestogen[7,8,9,25,36,37]

Consilient Health

PROGESTOGEN RELATED SIDE EFFECTS

Progestogen Side Effects

PMS-type symptoms, Irritability and Depression, Breast tenderness, Bloating, Headaches, Acne/greasy skin

Considerations:

1. Try a different Progestogen molecule- either as a single agent or with oestrogen in combination with HRT products.
See progestogen chapter for full details of progestogen.

2. Try minimising progestogen exposure - What is the minimum progestogen dose? The role of the progestogen part of HRT is to protect endometrium from the effects of the oestrogen and not as a therapeutic component for menopausal symptoms. There are studies to guide us as to how much progestogen would be required to ensure endometrial protection and they are:

Note: Progestogen doses outlined below are for women who are using ≤ 50mcg oestrogen patch dose or equivalent.

For non-menstruating patients, the minimum recommended Progestogen doses are:*

- 100mg Micronised progesterone daily
- 5mg Dydrogesterone daily**
- 2.5mg Medroxyprogesterone acetate
- Mirena (for 5 years)

For menstruating patients, the minimum recommended Progestogen doses are:*

- 200mg Micronised progesterone x 12 days/month
- 5mg Dydrogesterone daily x 12 days per month is recommended**
- 5mg Medroxyprogesterone acetate
- Mirena, Levonorgestrel available as a 52mg IUCD.

Long Cycle HRT

Long cycle progestogen regimes are sometimes recommended for patients with extreme progestogen sensitivity not improved by other options. This involves providing oestrogen all the time but only including a progestogen for 12 days every 3 months. Unfortunately patients will have side effects during these 12 days but they can schedule their progestogen days for a time that suits them better. The safety of 'Long Cycle Progestogen' HRT with regard to the lining of the womb is questionable and not routinely recommended. It is wise to offer ultrasound review of the endometrium for patients who can not use progestogen every month. Ideally this should be undertaken by a practitioner with specific menopause accreditation.

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

*Other progestogens, including norethisterone acetate / other doses of micronised progesterone are also available as Exempt Medicinal Products, information on the supply of these medicines can be provided from the manufacturer. Further information on Exempt Medicinal Products can also be found on the HPRA website, www.HPRA.ie
**Only 10mg Dydrogesterone available in Ireland.

Troubleshooting: Testosterone Risk[16,17,18]

Consilient Health

Testosterone Related Side Effects

Testosterone in doses that approximate physiological testosterone concentrations for premenopausal women is associated with mild increases in acne and body or facial hair but not clitoromegaly/ change in voice or alopecia.

Oral testosterone therapy (but not transdermal therapy) is associated with adverse lipid profiles. It has not been associated with increases in blood pressure, blood glucose or HBA1C levels.

There is no association with changes in breast density on mammography and current data suggests that short-term transdermal therapy does not impact breast cancer risk. Testosterone should be used with caution in women who have a history of hormone-sensitive breast cancer.[18]

See further information in Testosterone chapter.

Blood Testosterone levels should be measured at baseline and at 3 months to ensure they are within normal female range. Refer to BMS algorithm for guidance.

Trouble shooting: Unscheduled Bleeding[5,26,27,28]

Note - bleeding that occurs in a postmenopausal women who is not on HRT, always requires investigation!

Bleeding soon after starting HRT is common and is often a cause of concern and inconvenience for patients.

An inadequate progestogenic effect can result in endometrial proliferation and possibly hyperplasia and bleeding.
The main goal is to exclude treatable causes of bleeding and to rule out malignancy.

Bleeding may result from medical interventions and medications, or as a result of bleeding dyscrasias, fibroids, endometrial polyps, hyperplasia or from cervical disease, genital infections or other local causes.

Bleeding that occurs while on Sequential / Cyclical HRT:

Withdrawal bleed is normal and this should be discussed with the patient.
It should occur toward the end of or after progestogen containing phase of the cyclical regimen.
Unpredictable/ unexpected bleeding is common in the first 6 months after starting HRT.
Bleeding which is unpredictable, occurring not at the expected time, or excessively heavy should be investigated.

Bleeding occuring while on Continuous HRT:

In women who are more than 12 months from their LMP, bleeding is common within the first 6 months of initiating HRT.

Investigation is not required within the first three months of initiating HRT and may respond to modification of HRT doses / delivery systems. Bleeding that does not respond to these fixes must be investigated. Risk factors for endometrial cancer include:

- Raised BMI
- History of polycystic ovarian syndrome (PCOS)
- Use of unopposed oestrogen or tamoxifen
- Nulliparity
- Increasing age (>45)
- Type 2 diabetes
- Family history (having close relatives with endometrial cancer)
- Having had endometrial hyperplasia in the past
- Treatment with radiation therapy to the pelvis to treat another cancer

Troubleshooting: Unscheduled Bleeding[5,26,27,28,36,37]

Consilient Health

Bleeding that occurs beyond 6 months of use of HRT:

- Physical exam - exclude STI / cervical / local vulvovaginal causes of bleeding
- Discuss compliance
- Pelvic ultrasound;
- If on sequential HRT: aim to have ultrasound in the first week after bleeding starts
- Up to date cervical smear

Endometrial thickness > 5mm;

- Endometrial blind biopsy may miss focal pathology
- Refer to gynaecology for endometrial sampling/ hysteroscopy

Endometrial thickness < 5mm; Consider:

- Increasing to 21 days of progestogen (from 14) per cycle, if on sequential HRT
- Increasing the dose of progestogen for women taking continuous HRT
- Changing the progestogen to alternative stronger progestogen
- Decreasing oestrogen dose
- Mirena IUD

Tranexamic acid and mefanamic acid can be prescribed with HRT to reduce bleeding or dysmenorrhea

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Contraception During the Perimenopause[7,8,9,36,37*]

Consilient Health

HRT use in patients on the following contraceptive methods:

1. The Combined Pill, Patch and Ring: Some patients will get relief from their menopause symptoms by hormonal contraception. If a combined hormonal contraception (CHC) is indicated for and acceptable to the patient, CHC is a suitable alternative to HRT- "No break / short break" regimes should be used so as to minimise gaps in the therapeutic effects of the hormone. **Do not use CHC and HRT together.**

2. The Progestogen Only Pill (Contraception): Current POP users can use an oestrogen and progestogen HRT regime in addition to POP. Progestogen in contraception is generally not high enough to guarantee endometrial protection so the additional progestogen in the HRT product is required.

3. Depo-Provera injection: It is thought that the Depo-provera injection will protect the endometrium from HRT oestrogen (but there is no data to support this). Advice is patients commencing are prescribed a HRT containing oestrogen and progestogen to convey endometrial protection.

4. Implanon: This may not provide enough endometrial protection. Additional progestogen as part of a HRT regime must be provided.

5. Mirena: For the first 5 years after insertion the LNG progestogen from the Mirena will suffice for the progestogen component of a HRT regime. After 5 years in situ, the Mirena will have to be changed or that Mirena can be left in situ and an additional progestogen as part of a HRT regime must be provided.

6. Kyleena, Jaydess, Copper IUCD, Barrier and Natural contraception: Provide contraceptive cover during the perimenopause, patients who require HRT should be prescribed both the oestrogen and the progestogen components of HRT.

7. Yanae® is a non-hormonal copper intrauterine device for birth control and is effective for up to 5 years. It prevents pregnancy locally - within the uterus. As Yanae is hormone-free, patients who require HRT should be prescribed both the oestrogen and progestogen compenents of HRT.*

All patients at risk of pregnancy should be counselled about contraception.
Advice given is based on the experience of practitioners working in this area. Please refer to the SPC for all medicines.
* IUD Yanae® 5 year long acting reversible contraception, is a medical device. Always read the label

Special Considerations [7,8,9,29,30,33,34,35,36,37]

Migraine

Migraine, even migraine with aura, is not a contraindication to HRT use and may even be beneficial but some migraine sufferers may experience migraine flare up's. A cautious approach is recommended but there is no need to refer to a specialist. A non-oral route may provide a more stable delivery of the hormone and be preferable in migraine with aura sufferers.

Endometriosis

Oestrogen may aggravate dormant or settled endometrial deposits even after Hysterectomy +/- BSO so people with a past history of moderate to severe endometriosis should be considered for Oestrogen and Progestogen HRT as the addition of the progestogen may suppress any residual endometriotic tissue.

Premature Ovarian Insufficiency (POI)

POI is associated with significant increases in morbidity and mortality if not treated correctly. All patients should be assessed by an endocrinologist with a special interest in POI or a dedicated POI service. The need for oestrogen, progestogen and frequently testosterone replacement is often greater in this cohort and larger than standard doses of HRT are sometimes required. Even though POI is linked to subfertility, contraception is also required as there may be unpredictable ovarian follicular activity.

Epilepsy

Data to suggest that people with seizure disorder may experience a reduction in seizure control when initiating HRT / any oral sex hormone - advice is to start slow and low and TD. People using Rifampicin, phenytoin, barbiturates and phenylbutazone should avoid the progestogen NET as its metabolism is accelerated by these medications which will weaken the endometrial protection they provide. This applies to users of Noriday (3 daily) or the Evorel conti patch.[37]

Advice given is based on the experience of practitioners working in this area. Advice for Evorel Conti is as per SPC. Please refer to the relevant SPC for all other medicines.

Special Considerations [7,8,9,29,30,33,34,35,36,37]

Osteoporosis

50% of women & 20% of men will experience an osteoporosis-related fracture in their lifetime.[29]

- HRT is both a treatment and a prevention therapy for osteoporosis. Standard dose of MHT reduces the risk of femoral, vertebral and non-vertebral fractures.
- On cessation of HRT bone protection is rapidly lost.
- An alternative regime should be prescribed before stopping HRT.
- It is believed, but not proven, that the efficacy of HRT in reducing fracture risk is derived from low dose (25mcg) oestrogen[30].
- Postmenopausal women need a dietary reference intake (DRI) of 800 - 1000 iu of vitamin D and 1,000 mg to 1,500mg of elemental calcium in the postmenopausal period. This should be assessed for each individual, a calcium dietary calculator can be used such as the Osteoporosis Foundation Calcium Calculator on the www.osteoporosis.foundation website.[33,34,35].

Specialist menopausal medical advice and management is advised for the following cohort of symptomatic women:

- Women whose treatment within primary care settings does not improve their menopausal symptoms.
- Women who are experiencing on-going troublesome or clinically significant side effects further to treatment within primary care setting, e.g. bleeding.
- Women who have contraindicaitons to HRT.
- Women with a complex medical history.[33]

Advice given is based on the experience of practitioners working in this area. Please refer to the relevant SPC for all medicines.

Prescribing Information: Citidaron® [36]

Citidaron (Cytisinicline) Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics for full details.

Product name: Citidaron 1.5mg tablets Composition: 1.5mg of Cytisinicline (previously used name: cytisine) **Indication:** Smoking cessation and reduction of nicotine cravings in smokers willing to stop. Treatment goal is the permanent cessation of use of nicotine-containing products. **Posology and administration:** Adults: One pack (100 tablets) is suffcient for a complete treatment course of 25 days: Day 1-3: 1 tablet every 2 hours (maximum 6 per day); Day 4-12: 1 tablet every 2.5 hours (maximum 5 per day); Day 13-16: 1 tablet every 3 hours (maximum 4 per day); Day 17-20: 1 tablet every 5 hours (maximum 3 per day); Day 21-25: 1-2 tablets a day (maximum 2 per day). Stop smoking no later than 5th day of treatment; continuing smoking may aggravate adverse reactions. In case of treatment failure, discontinue; may be resumed after 2 to 3 months. **Special populations:** *Renal or hepatic impairment:* no clinical experience; not recommended. *Elderly (over 65 years):* limited clinical experience; not recommended. *Paediatric population (under 18 years):* Safety and efficacy not established; not recommended. **Method of administration:** Orally with water. **Contraindications:** Hypersensitivity to active substance or excipients; unstable angina; recent myocardial infarction or stroke; clinically signiffcant arrhythmias; pregnancy and breastfeeding. **Warnings and precautions (see SmPC for full details):** Only for patients with serious intention of weaning off nicotine. Patient should be aware that simultaneous smoking or use of nicotine-containing products could lead to aggravated adverse reactions of nicotine. Use with caution in: ischemic heart disease, heart failure, hypertension pheochromocytoma, atherosclerosis and other peripheral vascular diseases, gastric and duodenal ulcer, gastroesophageal reflux disease, hyperthyroidism, diabetes and schizophrenia. Polycyclic aromatic hydrocarbons in tobacco smoke induce metabolism by CYP 1A2 (and possibly CYP 1A1). Stopping smoking may slow metabolism and raise blood levels of such drugs. Potentially clinically important if narrow therapeutic window, e.g. theophylline, tacrine, clozapine, ropinirole. Levels of products partly metabolised CYP1A2 e.g. imipramine, olanzapine, clomipramine, fluvoxamine, may also increase; data are lacking, clinical significance unknown. Limited data indicate metabolism of flecainide and pentazocine may be induced by smoking. Be aware of serious neuropsychiatric symptoms in patients attempting to quit smoking, with or without treatment, including: depressed mood, rarely including suicidal ideation and suicide attempt; exacerbation of underlying psychiatric illness (e.g. depression) - take care in these patients and advise accordingly. (See Pregnancy). **Pregnancy:** Contraindicated. Women of childbearing potential must use highly effective contraception. If on systemically acting hormonal contraceptives, add a second barrier method. **Breastfeeding:** Contraindicated. **Fertility:** No data available. **Undesirable effects: Very Common (≥1/10):** change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, tachycardia, hypertension, dry mouth, diarrhea, nausea, changes flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen), rash, myalgia, fatigue **Common (≥1/100 to <1/10):** diffculty in concentration, slow heart rate, abdominal distension, burning tongue, malaise. **Price:** https://www.consilienthealth.ie/our-medicines/pricing-of-our-medicines/

Legal Classification: POM. MA number: PA22714/001/001.
Marketing Authorisation Holder: Aflofarm Farmacja Polska Sp. z o.o. CRN00D3GH, Partyzancka 133/151 Pabianice 95-200 Poland. Further information is available on request from Consilient Health Ltd, Block 2A Richview Offce Park, Clonskeagh, Dublin 14.
Job Code: IE-CYT-1(5)
Date of preparation: November 2025

Adverse events should be reported. Reporting forms and information are available from HPRA Pharmacovigilance on the HPRA website www.hpra.ie.

Adverse events should also be reported to Consilient Health at drugsafety@consilienthealth.com or 012057766.

PRESCRIBING INFORMATION

Prescribing Information: Mysimba® [37]

PRESCRIBING INFORMATION

Mysimba Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics for full details.

Mysimba 8 mg/90 mg prolonged-release tablet (8 mg naltrexone hydrochloride, equivalent to 7.2 mg naltrexone, and 90 mg bupropion hydrochloride, equivalent to 78 mg bupropion). **Therapeutic indications:** As an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of: ≥ 30 kg/m2 (obese), or ≥ 27 kg/m2 to (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension). Treatment with Mysimba should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight. **Posology:** Initial treatment, the dose should be escalated over a 4-week period as follows: **Week 1:** One tablet in the morning, **Week 2:** One tablet in the morning and one tablet in the evening, **Week 3:** Two tablets in the morning and one tablet in the evening, **Week 4** and onwards: Two tablets in the morning and two tablets in the evening(maximum recommended daily dose). Evaluate the need for continued treatment after 16 weeks and annually thereafter. The cardiovascular risks of Mysimba when given for longer than a year have not been fully determined. Discontinue after one year if patients have not maintained ≥ 5% weight loss; Conduct annual assessments to ensure no adverse change in cardiovascular risk before continuing treatment. **Missed dose:** patients should not take an additional dose, but take the next dose at the usual time. **Special populations:** Naltrexone/bupropion should be used with caution in patients **over 65 years of age and is not recommended in patients over 75 years of age.** Naltrexone/bupropion is **contraindicated** in patients with **end-stage renal failure**. In patients with moderate or severe renal impairment, the maximum recommended daily dose is two tablets (one tablet in the morning and one tablet in the evening). It is recommended that patients with moderate or severe renal impairment initiate treatment with one tablet in the morning for the first week of treatment and escalate to one tablet in the morning and one tablet in the evening from week 2 onwards. For individuals who are at elevated risk for renal impairment, in particular patients with diabetes or elderly individuals, estimated glomerular filtration rate (eGFR) should be assessed prior to initiating therapy with naltrexone/bupropion. Patients with **hepatic impairment:** naltrexone/bupropion is contraindicated in patients with **severe hepatic impairment**. For with mild hepatic impairment, the maximum recommended daily dose is two tablets. Degree of hepatic impairment should be assessed using the Child-Pugh score. **Paediatric population children and adolescents below 18:** Contraindicated. **Method of administration:** The tablets should be swallowed whole with some water and preferably with food, and should not be cut, chewed or crushed. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the excipients, uncontrolled hypertension, current seizure disorder or a history of seizures, a known central nervous system tumour, undergoing acute alcohol or benzodiazepine withdrawal, history of bipolar disorder, receiving any concomitant treatment containing bupropion or naltrexone, current or previous diagnosis of bulimia or anorexia nervosa, currently dependent on opioids including opioid-containing medication, treated with opioids agonists used in opioid dependence, or in acute opioid withdrawal, receiving concomitant administration of monoamine oxidase inhibitors (MAOI). **Special warnings and precautions for use:** The safety and tolerability of naltrexone/bupropion should be assessed at regular intervals. **Suicide and suicidal behaviour:** Monitor patients during treatment, as bupropion, an antidepressant, may increase risk especially in young adults and during early treatment or dose changes.**Seizures and associated conditions:** The co-administration of antipsychotics, antidepressants, antimalarials, tramadol, theophylline, systemic steroids, quinolones and sedating antihistamines may lower the seizure threshold, and the consumption of alcohol during naltrexone/bupropion treatment should be minimised or avoided. Opioid containing medications including analgesics: ensure opioids are stopped for 7-10 days before starting naltrexone/bupropion, and discontinue it at least 3 days before any necessary opioid use, without increasing the opioid dose beyond standard level. **Allergic reactions have been reported:** A patient should stop taking naltrexone/bupropion and consult a doctor if experiencing allergic or anaphylactoid/anaphylactic reactions during treatment. **Severe cutaneous adverse reactions (SCARs):** such as Stevens-Johnson syndrome (SJS) and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported Advise patients of skin reaction symptoms and monitor closely. If symptoms occur discontinue naltrexone/bupropion immediately and consider an alternative treatment (as appropriate) do not restart naltrexone/bupropion treatment. **Elevation of blood pressure** has been observed with naltrexone/bupropion treatment. Measure blood pressure and pulse before starting naltrexone/bupropion and regularly thereafter; discontinue if there are sustained, clinically relevant increases. **Cardiovascular disease:** There is no clinical experience establishing the safety of naltrexone/bupropion in patients with a recent history of myocardial infarction, unstable heart disease or NYHA class III or IV congestive heart failure however use should be with caution. **Brugada Syndrome:** Caution is advised in patients with Brugada syndrome or a family history of cardiac arrest or sudden death. **Hepatotoxicity:** In naltrexone/bupropion completed clinical studies, where naltrexone hydrochloride daily doses ranged from 16 mg to 48 mg, drug-induced liver injury (DILI) was reported. A patient with suspected DILI should stop taking naltrexone/bupropion. **Serotonin Syndrome:** There have been post-marketing reports of serotonin syndrome when co-administered with a serotonergic agent. if concomitant treatment with other serotonergic agents is warranted, careful observation of the patient is advised, and treatment discontinuation should be considered if symptoms develop. Data in animals suggest a potential for abuse of bupropion, however studies in humans and extensive clinical expertise have shown low abuse potential. **Influence on the ability to drive and use machines:** Naltrexone/bupropion has been associated with somnolence and episodes of loss of consciousness. Patients **must be advised to exercise caution while driving or operating** machines during treatment. **Lactose:** Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption use contraindicated. Consult educational materials before prescribing. **Patients should be advised to carry the patient card with them at all times. Interaction with other medicinal products and other forms of interaction:** concomitant MAOIs oropioid analgesics must not be used. Drugs metabolised by cytochrome P450 (CYP) enzymes and OCT2 substrates have potential for interaction. **Pregnancy** limited data available and the drug should not be used in pregnant or women trying to become pregnant. **Breast-feeding:** Naltrexone and bupropion and their metabolites are excreted in human milk and use is contraindicated. **Fertility:** No data available. **Undesirable effects:** The most frequent adverse reactions in clinical studies were nausea (very common), constipation (very common), vomiting (very common), dizziness (common), and dry mouth (common). The most frequent adverse reactions leading to discontinuation with naltrexone/bupropion were nausea (very common), headache (very common), dizziness (common) and vomiting (very common). **Overdose:** There is no clinical experience with overdose with combined use of bupropion and naltrexone. **Excipients: Tablet core:** contains Lactose monohydrate (For a full list see the SmPC). **Shelf life:** 30 months. **Storage:** Do not store above 30°C. Nature and contents of container: PVC/PCTFE/PVC/Aluminium blisters. **Pack sizes:** 28, 112 tablets. **MARKETING AUTHORISATION HOLDER: Orexigen Therapeutics Ireland Limited,** 9-10Fenian Street, Dublin 2, Ireland. **MARKETING AUTHORISATION NUMBER(S):** EU/1/14/988/001-002. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION: 26 March 2015.** Date of latest renewal: **16 January 2020**. Detailed information on this medicinal product is available on www.hpra.ie. Adverse events should be reported to Orexigen Therapeutics Ireland Limited (+3531800849099) or use the link to report directly to Currax.MI@primevigilance.com . Cost NWP: **€83.00** IE-MYS-164(6)

Preparation Date: August 2025

For current Price: https://www.consilienthealth.ie/our-medicines/pricing-of-our-medicines/

Prescribing Information: Blissel® Vaginal Gel[42]

BLISSEL® (ESTRIOL 50 micrograms/1g) VAGINAL GEL PRESCRIBING INFORMATION: Please refer to Summary of Product Characteristics (SmPC) before prescribing. **ACTIVE INGREDIENT:** 1g vaginal gel contains 50 micrograms estriol. **INDICATIONS:** Treatment of symptoms of vaginal atrophy due to estrogen deficiency in postmenopausal women. **DOSAGE AND ADMINISTRATION:** Use the lowest effective dose for the shortest duration. **Treatment initiation or reinstitution:** One applicator-dose per day for 3 weeks at bedtime. Only initiate local estrogen therapy for symptoms that adversely affect quality of life. Take a complete personal and family medical history. Use this, and the contraindications and warnings for use, to guide physical (including pelvic and breast) examination. Treat vaginal infections before starting therapy. **Maintenance treatment:** One applicator-dose twice weekly emptied into vagina at bedtime. **Evaluation:** Evaluate treatment continuation after 12 weeks. Conduct periodic check-ups and investigations, adapted to the individual, including mammography, in accordance with accepted screening practices. Advise of breast changes that should be reported. Appraise the risks and benefits at least annually and continue only if the benefit outweighs the risk. Administer a missed dose as soon as remembered. Skip doses 12 hours or more overdue and administer the next dose at the normal time. **Administration:** Empty dose-marked applicator into vagina in accordance with instructions in the information leaflet. **CONTRAINDICATIONS:** Known, past or suspected breast cancer, known or suspected estrogen-dependent malignant tumour, undiagnosed genital bleeding, untreated endometrial hyperplasia, previous idiopathic or current venous thromboembolism, active or recent arterial thromboembolic disease, known thrombophilic disorders, acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal, porphyria, hypersensitivity to the active substance or to any of the excipients. Discontinue immediately if a contraindication is discovered and in cases of jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache or pregnancy. **SPECIAL WARNINGS AND PRECAUTIONS:** Do not combine with estrogen preparations for systemic treatment. Intravaginal applicator may cause minor local trauma, especially in women with serious vaginal atrophy. Excipients may cause allergic reactions (possibly delayed). Close supervision of patients with current, previous, or where the condition has been aggravated during pregnancy, or previous hormone treatment: Leiomyoma or endometriosis, risk factors for thromboembolic disorders or estrogen-dependent tumours, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis. Addition of a progestogen is not recommended. Endometrial safety of long-term (> one year), or repeated use of, vaginal oestrogen is uncertain so treatment should be reviewed at least annually. Investigate breakthrough bleeding or spotting occurring at any time on therapy to exclude endometrial malignancy. Caution in women who have undergone hysterectomy because of endometriosis, especially if there is residual endometriosis. Risks associated with systemic HRT apply to a lesser extent for vaginally applied oestrogens but they should be considered in case of long term or repeated use. Epidemiological evidence from a large meta-analysis suggests no increase in risk of breast cancer in women with no history of breast cancer taking low dose vaginally applied oestrogens. It is unknown if low dose vaginal oestrogens stimulate recurrence of breast cancer. Increased risk of ovarian cancer, venous thromboembolism (VTE), coronary artery disease and ischaemic stroke associated with systemic HRT. Generally recognised risk factors for VTE include use of estrogens, older age, major surgery, prolonged immobilisation, obesity (BMI > 30 kg/m2), pregnancy/ postpartum period, systemic lupus erythematosus and cancer. No consensus about the possible role of varicose veins in VTE. Estrogens with systemic effects may cause fluid retention or increase of plasma triglycerides. Therefore, careful observation of patients with heart diseases or impaired renal function or with pre-existing hypertriglyceridemia during the first weeks of treatment is recommended. No systemic effects expected with Blissel low dose estriol vaginal gel. Careful observation in severe renal insufficiency as levels of circulating estriol may be increased. **INTERACTIONS:** No interaction studies have been performed. Due to vaginal administration, and minimal systemic absorption, no clinically relevant interactions are expected. Consider interactions with other locally applied vaginal treatments. **FERTILITY, PREGNANCY, LACTATION:** No fertility data available. Not indicated during pregnancy. Withdraw treatment immediately if pregnancy occurs. No data available on exposed pregnancies. Not indicated during lactation. **DRIVING:** No influence on ability to drive and use machines. **UNDESIRABLE EFFECTS:** Very common: None. Common: Pruritus genital, application site pruritus, pruritus. Consult SmPC in relation to less common side effects and class effects associated with systemic HRT. **PHARMACEUTICAL PRECAUTIONS:** Store below 25°C. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION HOLDER:** Italfarmaco S.A., San Rafael 3, 28108 Alcobendas (Madrid), Spain. Marketed and distributed in Ireland by Consilient Health (Ireland) Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y045. E-mail: irishoffice@consilienthealth.com.

Price: www.consilienthealth.ie/our-medicines/pricing-of-our-medicines/

Pack size: 30g **Marketing Authorisation Number:** PA2102/001/001

Adverse events should be reported.
Reporting forms and information can be found at http://www.hpra.ie/homepage/medicines/safety-information/reporting- suspected-side-effects. Adverse events should also be reported to Consilient Health (Ireland) Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y045 or drugsafety@consilienthealth.com

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2102-001-001_09082022145537.pdf

Job bag: IE-BLS(5) **Date of Preparation** August 2025.

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PRESCRIBING INFORMATION

1. Cano A, et al. Menopause. 2012;19(10):1130-9. 2. Blissel 50 micrograms/g vaginal gel. Summary of product characteristics. 3. Lazaro-Carrasco de la Fuente J, et al. J Menopausal Med. 2022;28(2):60-69.

References*

REFERENCES

1 British Menopause Society Guidelines and Tools for Clinicians, https://thebms.org.uk/publications/tools-for-clinicians

2 International Menopause Society Recommendations, https://www.imsociety.org/statements/ims-recommendations/

3 Patient.ie, Patient Health Questionnaire, available on www.patient.info

4 BMS & WHC's (2020) recommendations on hormone replacement therapy in menopausal women, https://thebms.org.uk/publications/consensus-statements/bms-whcs-2020-recommendations-on-hormone-replacement-therapy-in-menopausal-women/

5 S. R. Goldstein & M. A. Lumsden (2017): Abnormal uterine bleeding in perimenopause, Climacteric, DOI: 10.1080/13697137.2017.1358921

6 Marsden J. (2019) British Menopause Society consensus statement: The risks and benefits of HRT before and after a breast cancer diagnosis. Post Reproductive Health. 2019;25(1):33-37. https://journals.sagepub.com/doi/full/10.1177/2053369119825716

7 MIMS Ireland (December 2022) , MPI Media, Section: Menopausal Disorders

8 The Health Products Regulatory Authority, Medicines, www.HPRA.ie

9 Irish Pharmaceutical Healthcare Association, Medicines, www.medicines.ie

10 Health Products Regulatory Authority, Exempt Medical Products, www.hpra.ie

11 Mariani L, et al (2013) Vaginal atrophy in breast cancer survivors: role of vaginal estrogen therapy. Gynecol Endocrinol. January

12 Streff A, et al. (2021) Changes in serum estradiol levels with Estring in postmenopausal women with breast cancer treated with aromatase inhibitors. Support Care Cancer. January

13 Pavlović RT, et al (2019) The Safety of Local Hormonal Treatment for Vulvovaginal Atrophy in Women With Estrogen Receptor-positive Breast Cancer Who Are on Adjuvant Aromatase Inhibitor Therapy: Meta-analysis. Clin Breast Cancer. Dec.

14 Kendall A, et al (2006) Caution: Vaginal estradiol appears to be contraindicated in postmenopausal women on adjuvant aromatase inhibitors. Ann Oncol.

15 Newton K et al (2008), Reprint of The Herbal Alternatives for Menopause (HALT) Study: background and study design, Maturitas, 2008 Sep-Oct;61(1-2):181-93, https://pubmed.ncbi.nlm.nih.gov/19434890/

16 Davis et al (2019) Global Consensus Position Statement on the use of testosterone therapy for women, in Climacteric, https://doi.org/10.1080/13697137.2019.1637079

17 Hamoda H, Panay N, Arya, R & Savvas M on behalf of The British Menopause Society and Women's Health Concern (2016). The British Menopause Society & Women's Health Concern 2016 recommendations on hormone replacement therapy in menopausal women. Post Reproductive Health; 22(4): 165-183.

18 Maclaran K, Panay N. (2012) The safety of postmenopausal testosterone therapy. Women's Health (Lond Engl). 8(3):263-75.

19 NICE Guidelines Summary (2015) , Menopause, Diagnosis and Management from Guidelines to practice , November, https://www.nice.org.uk/guidance/ng23

20 Canonico et al (2016) Postmenopausal Hormone Therapy and Risk of Stroke, Stroke, Jul; 47(7): 1734–1741. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4927222/

21 Collaborative Group on Hormonal Factors for Breast Cancer. (1997) Breast cancer and hormone replacement therapy: collaborative reanalysis from 51 individual epidemiological studies. Lancet 350: 1047–1060.

22 National Institute for Health and Care Excellence.(2013) Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer (CG164), www.nice.org.uk/guidance/cg164

23 North Americal Menopause Society (2017) Hormone Therapy Position statement, Menopause; 24: 728–753.

24 Womens Health Concern/ British Menopause Society, Infographic re. Understanding the risks of breast cancer. https://thebms.org.uk/wp-content/uploads/2023/01/WHC-Infographics-JANUARY-2023-BreastCancerRisks.pdf

25 British Menopause Society, Progestogens and endometrial protection - tool for clinicians, https://thebms.org.uk/wp-content/uploads/2021/10/14-BMS-TfC-Progestogens-and-endometrial-protection-01H.pdf

References

REFERENCES

26 American College of Obstetrics and Gynecology (2012) . Practice Bulletin No. 128, Diagnosis of abnormal uterine bleeding in reproductive aged women. Obstet Gynecol , 120 :197–206

27 Abdullahi Idle S and Hamoda H (2019) Outcomes of endometrial assessment in women with unscheduled bleeding on hormone replacement therapy. Post Reproductive Health 25(2): 95-99.

28 Burbos N, Musonda P, Duncan TJ, et al. (2012) Postmenopausal vaginal bleeding in women using hormone replacement therapy. Menopause International 18: 5-9.

29 Johnell O and Kanis JA (2006) "An estimate of the worldwide prevalence and disability associated with osteoporotic fractures." Osteoporos Int 17:1726–1733

30 Irish Osteoporosis Society , Prescribed Medication for Osteoporosis, https://www.irishosteoporosis.ie/information-support/getting-the-best-out-of-your-medication/

31 British Menopause Society (2021), Consensus Statement, Non-Hormone Based Treatments, https://thebms.org.uk/publications/consensus-statements/non-hormonal-based-treatments-menopausal-symptoms/

32 Cardoso F., et al. Elinzanetant for Vasomotor Symptoms from Endocrine Therapy for Breast Cancer. N Engl J Med 2025. DOI: 10.1056/NEJMoa2415566

33 ICGP, Dr Caoimhe Hartley, Dr Ciara McCarthy, Dr Noirin Herlihy, Diagnosis and Management of menopause in general practice, Quick reference guide. Published October 2022.

34 Osteoporosis Foundation Calcium Calculator, https://www.osteoporosis.foundation/educational-hub/topic/calcium-calculator

35 The Irish Osteoporosis Society, Calcium and Vitamin D, https://www.irishosteoporosis.ie/information-support/vitamin-d-osteoporosis/

36 Citidaron SPC, available on medicines.ie

37 Mysimba SPC, available on medicines.ie

38 Evorel Conti SPC, available on www.medicines.ie

39. Chlebowski et al (2020), Association of Menopausal Hormone Therapy With Breast Cancer Incidence and Mortality During Long-term Follow-up of the Women's Health Initiative Randomized Clinical Trials, JAMA. Jul 28; 324(4): 369–380. https://jamanetwork.com/journals/jama/fullarticle/2768806

40. Li et al (2021), The Fractional CO_2 Laser for the Treatment of Genitourinary Syndrome of Menopause: A Prospective Multicenter Cohort Study in Lasers in Surgery and Medicine 53:647–653

41. Health Service Executive, Breast Cancer in Women, https://www2.hse.ie/conditions/breast-cancer-women.

42. The British Menopause Society , Bioidentical HRT, https://thebms.org.uk/publications/consensus-statements/bioidentical-hrt/

43. Blissel SPC available on www.medicines.ie

* All websites accessed August 2025.

For further information and support visit www.Consilienthealth.ie

Acknowledgements

We sincerely thank Dr. Deirdre Lundy and Dr. Caoimhe Hartley who developed the patient management guide in conjunction with Consilient Health

Code: IE-WH-260, Date of preparation: December 2025