

naltrexone HCl/bupropion HCl
8mg/90mg Prolonged-Release Tablets

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For further information please visit:
www.mysimba.ie and www.consilienthealth.ie

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may experience.



INTRODUCTION

Your doctor has given this booklet to you because you have been prescribed Mysimba. Together with diet and exercise, Mysimba may help you achieve the optimal weight for you so that you can lead a healthier life. There is a lot of information to take in when you visit your doctor for the first time. We hope this booklet will help you better understand your Mysimba treatment and answer any questions.

Please read on to:

- Learn how Mysimba works and how to take it
- Understand what benefits you might get from Mysimba
- Be aware of potential side effects
- Know when it is important to speak with your doctor or pharmacist
- Find ideas on how to follow your treatment, diet and exercise plan and feel more comfortable and confident in your treatment

SOME INFORMATION FOR YOU ON MYSIMBA

What is Mysimba?^{1,2}

Mysimba is a prescription-only, weight-loss medicine, for adults over 18 years of age.

It contains two active substances^{1,2}:

- Naltrexone hydrochloride
- Bupropion hydrochloride

You have been prescribed Mysimba to help you achieve your optimal weight; together with a reduced calorie diet and increased physical exercise.

Mysimba is approved for use in adults (≥ 18 years) with an initial body mass index (BMI) of 30 or greater. It can also be given to adults with a BMI between 27 and 30 if they have additional weight-related conditions, such as controlled high blood pressure (hypertension), type 2 diabetes or high levels of lipid (fat) in the blood.¹ If you have been taking Mysimba for 16 weeks and have not lost at least 5% of your initial body weight, your doctor may discontinue your prescription. Your doctor may also recommend stopping treatment if there are concerns about any of the following:

- Increase in blood pressure
- Other side effects
- or you are put on a new medication

1. Mysimba SmPC 2025 available on [medicines.ie](https://www.medicines.ie) or www.ema.europa.eu.

2. Mysimba Patient Information Leaflet 2025 available on [medicines.ie](https://www.medicines.ie) or www.ema.europa.eu.

Recommendations on annual review

Your healthcare professional will ask you to attend an annual review to check that there has been no change in your cardiovascular risk and that you are maintaining your weight loss.

It is recommended that treatment with **Mysimba** is stopped after one year if you have not maintained a loss of at least 5% of your initial body weight.

What is body mass index (BMI)?

Your BMI is a measure of your weight compared to your height and is often used by health care professionals as an initial screening tool to identify potential weight-related health risks. For most adults, a BMI of:

- **25-29.9 means you fall into the overweight category**
- **30-39.9 means you are living with obesity level 1**
- **40 or above means you are living with severe obesity**

BMI is calculated as your body weight in kilograms (kg) divided by your height squared in metres (m²). You often see this formula written as BMI = weight in kg/height m².

It's important to note that while BMI is a useful screening tool, it does have limitations. For instance, it does not take into account factors such as your muscle mass, bone density, waist circumference, or distribution of body fat, which can vary among individuals. Therefore, BMI alone may not provide a comprehensive assessment of your overall health or body composition.

To calculate your BMI please visit

<https://www.safefood.net/bmi-calculator>

How does my Mysimba work?

Mysimba contains 2 active substances: naltrexone hydrochloride and bupropion hydrochloride. It is used in obese or overweight adults to manage weight together with a reduced calorie diet and physical exercise. This medicine works on areas of the brain involved in the control of food intake and energy expenditure.^{1,2}



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How effective is Mysimba^{1,2,3}

In clinical trials (4,500 patients), patients on Mysimba experienced significant weight loss in conjunction with a reduced-calorie diet and increased physical activity. Over half of patients lost $\geq 5\%$ body weight loss at end of week 16 on treatment. This group of patients continued to maintain or increase their weight loss at one year, with an average weight loss of 11.7% of their body weight.³ Nearly 1 in 3 people achieved at least 15% body weight loss at 1 year.³ Mysimba helps to reduce appetite and manage food cravings, making it easier for patients to make healthier food choices.

In addition to weight loss, Mysimba has shown positive effects on other health measures, including fat levels in the blood, and blood sugar control. These improvements contribute to reducing the risk of other complications related to excess weight.

If you do not lose 5% or more of your body weight by end of week 16, do not despair, Mysimba may not work for you, however there are other medications available that might be better suited for you. Please ask your doctor who can help you.

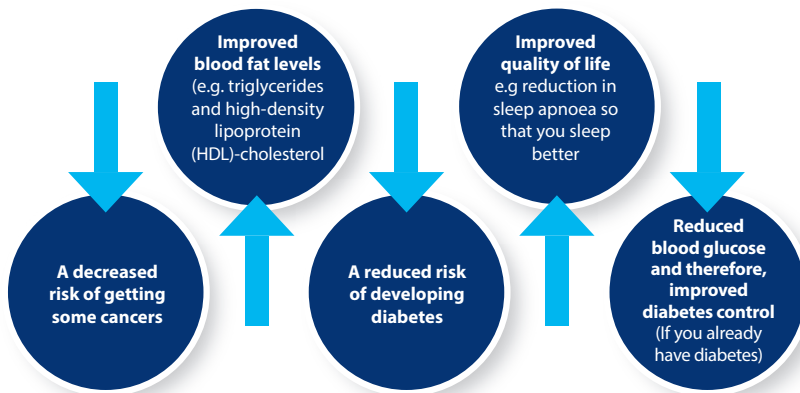
As you start to lose weight, it is important to continue making healthy lifestyle choices and continue taking Mysimba, which may help you maintain your weight loss.

What are the benefits of controlled weight loss?

A healthier weight can help alleviate the following conditions:

- Foot, hip or knee pain • Heartburn • Acid reflux
- Shortness of breath • Sleep apnoea • Joint pain

Studies have also shown that losing 5-10% of body weight can be beneficial to your overall health. These benefits may include:



Please note that Mysimba is not indicated for the treatment of these conditions.

WHAT DO I NEED TO KNOW BEFORE I TAKE MYSIMBA?

Mysimba is not suitable for you if you^{1,2}

- Are allergic to naltrexone or bupropion or to any of the other ingredients in this medicine
- Have abnormally high blood pressure or uncontrolled blood pressure
- Have a condition that causes fits (seizures) or a history of fits
- Have a brain tumour
- Are usually a heavy drinker and you have just stopped drinking alcohol, or are going to stop while you are taking Mysimba
- Have recently stopped taking sedatives or medicines to treat anxiety or depression, or if you are going to stop them while you are taking Mysimba
- If you have or have had a bipolar disorder (extreme mood swings)
- Are using any other medicines that contain bupropion or naltrexone
- Have an eating disorder or have had one in the past
- Are currently dependent on opioids, or taking opioids for the treatment of dependence (for example methadone or buprenorphine), or you are going through acute withdrawal (cold turkey)
- Are taking medicines for depression or Parkinson's disease called monoamine oxidase inhibitors (MAOIs), or have taken them in the last 14 days
- Have liver disease or end stage kidney failure
- Are pregnant, planning to become pregnant or suspect you are pregnant or are breast feeding



Please refer to the Mysimba Package leaflet for the complete list of contraindications. You can also speak with your doctor to identify if Mysimba is suitable for you or not.

You should talk to your doctor especially if: You have high blood pressure, uncontrolled coronary artery disease (a heart disease caused by poor blood flow in the blood vessels of the heart), have or have had cerebrovascular disease (a condition affecting the circulation of blood in the brain), a history of mania (feeling elated or over-excited, which causes unusual behaviour) or are taking medicines for depression. Also speak to your doctor if you have any liver or kidney problems before you start Mysimba.

It is also advisable to talk to your doctor or pharmacist before taking Mysimba if you:

- Feel depressed, contemplate suicide, have a history of attempting suicide or any other mental health concerns
- Have had a serious head injury or head trauma
- Regularly drink alcohol
- Regularly use medicines to help you sleep (sedatives)
- Are currently dependent on, or addicted to, cocaine or other stimulating products
- Have diabetes for which you use insulin or oral medicines that may cause low sugar levels in your blood (hypoglycaemia)
- Are taking medicines that may increase the risk of seizures
- Have Brugada syndrome or a family history of cardiac arrest or sudden death



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HOW SHOULD I START TAKING MYSIMBA?

At first, you should take one tablet once a day in the morning.
The dose of Mysimba is gradually increased over four weeks.

Week 1: one tablet once a day – in the morning.

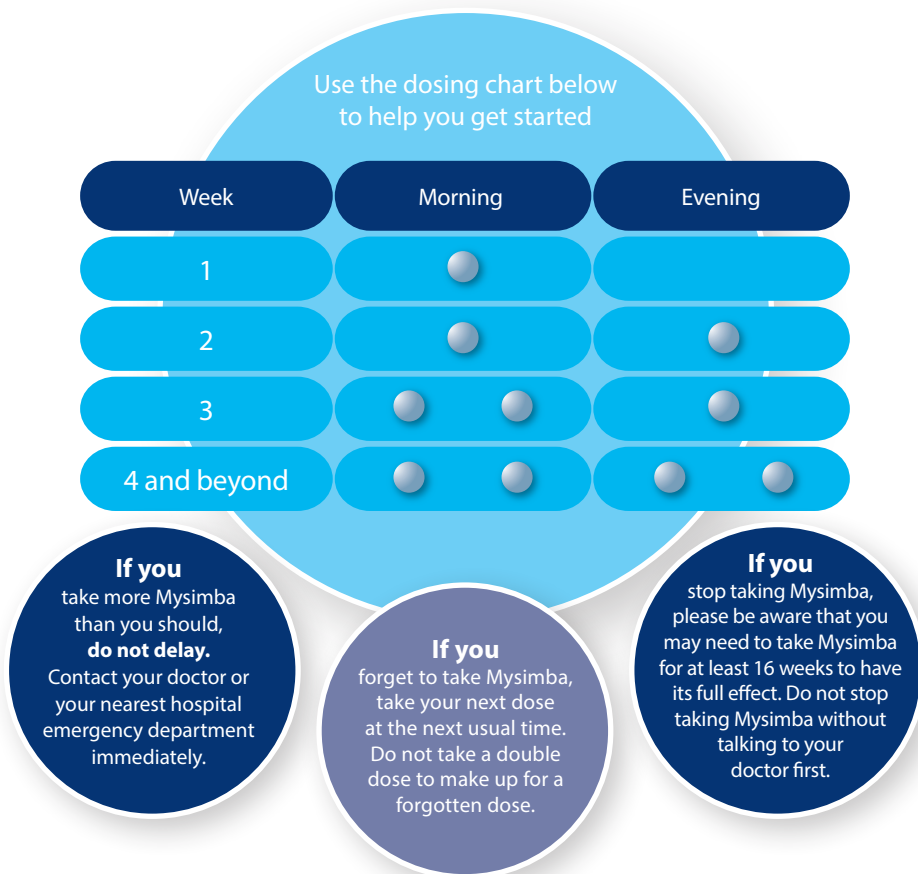
Week 2: one tablet twice a day – one in the morning and one in the evening.

Week 3: three tablets every day – two in the morning and one in the evening.

Week 4 and onward: two tablets twice a day – two in the morning and two in the evening.

The maximum recommended daily dose of Mysimba is two tablets taken twice a day.
You should take this medicine by mouth, and preferably with food^{1,2}.

Always take Mysimba as directed by your doctor. Some health conditions or medications may lead your doctor to reduce your dose. Keep your doctor informed of changes to your health and medication status while taking Mysimba.



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WHAT SHOULD I EXPECT WHEN TAKING MYSIMBA?

Like all medications, Mysimba can cause side effects, although not everyone gets them

Potential side effects

Very common side effects that may affect more than 1 in 10 people taking Mysimba are:^{1,2}

- Feeling sick (nausea), being sick (vomiting)
- Constipation
- Headache

Nausea is most common in the first month as the dose is being increased, usually resolving in two to four weeks. Vomiting is less common and typically resolves within a week.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Your doctor can help you find ways to manage side effects, or may recommend you stop taking Mysimba.

Tell your doctor about any side effect that bothers you or doesn't go away.
This includes any possible side effects not listed here.

For more information on Mysimba, please read the Patient Information Leaflet inside your package of Mysimba medication.

Seizures are rare and may affect up to 1 in 1,000 people taking Mysimba. If you have a seizure, you should stop taking Mysimba and consult your doctor immediately.

WHAT SHOULD I AVOID WHEN TAKING MYSIMBA?

Avoid alcohol when taking Mysimba

As drinking alcohol may increase your risk of seizures. There have also been rare reports of mental disorders and reduced alcohol tolerance in patients on Mysimba so the advice is to minimise or avoid alcohol altogether.

Do not take Mysimba if pregnant or breastfeeding

You should not take Mysimba during pregnancy, or while breastfeeding.

Ask your doctor or pharmacist for advice before taking Mysimba, if you:

- Think you may be pregnant
- Are planning to have a baby

Driving and using machines

Mysimba may make you feel sleepy or dizzy and this may make you less able to concentrate and react, especially at the beginning of treatment or when increasing the dose. If you experience these side effects, it is best to avoid driving or operating machines until these have resolved.

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Can I take my other medicines with Mysimba?

Tell your doctor if you are taking, have recently taken or might take any other medicines.^{1,2}

Before taking Mysimba, tell your doctor about ALL medicines you take, including prescription and non-prescription drugs, over-the-counter medications, supplements, and herbal remedies.

This is especially important for:

- Medicines for depression, mental health, epilepsy, or Parkinson's disease
- Steroids, malaria prevention drugs, certain antibiotics, and antihistamines
- Medications for diabetes, sleep, high blood pressure, or heart rhythm
- Some cancer treatments
- HIV/AIDS medications
- Digoxin (for heart conditions)

Your doctor may need to monitor you closely or adjust doses due to potential interactions or increased risk of side effects, including seizures.

Mysimba may make other medicines less effective when taken at the same time.

Do not take Mysimba with Monoamine Oxidase Inhibitors (MAOIs) or Opioid-containing medicines.^{1,2}

MAOIs include medicines to treat depression or Parkinson's disease. Stop at least 14 days before starting Mysimba.

Opioid containing medicines include medicines for pain, cough and cold (such as Codeine), addiction, or diarrhoea. Stop 7-10 days before starting Mysimba.

If you need opioids (e.g. during surgery) while taking Mysimba, you should stop taking Mysimba at least 3 days before. Naltrexone contained in Mysimba blocks the effects of opioids for several days after you stop taking Mysimba.

For more information on Mysimba, please read the Patient Information Leaflet inside your package of Mysimba medication.

Further information can also be found at
www.mysimba.ie and
www.consilienthealth.ie

Note:

A patient card is included inside each pack of Mysimba.

Write your name, your doctor's name and telephone number on this card. Carry the patient card with you at all times. It is important that you inform health care professionals that you are taking Mysimba in case of surgery.

1. Mysimba SmPC 2025 available on medicines.ie or www.ema.europa.eu.

2. Mysimba Patient Information Leaflet 2025 available on medicines.ie or www.ema.europa.eu.

Allergic Reactions

You should stop taking Mysimba immediately and consult your doctor if you are experiencing any symptoms of an **allergic reaction** such as swelling of the throat, tongue, lips, or face, difficulty swallowing or breathing, dizziness, fever, rash, pain in the joints or in the muscles, itching or hives after taking this medicine.

Serious skin reactions, including Stevens-Johnson syndrome and acute generalised exanthematous pustulosis (AGEP), have been reported in association with Mysimba treatment. Stop using Mysimba and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.

TIPS TO HELP YOU FOLLOW YOUR DAILY MYSIMBA ROUTINE

It is not always easy to follow a medication routine, especially when taking a long-term treatment. Below are some tips and tools to help you adhere to your daily Mysimba routine, so that you can get on with your life!



Plan a routine

- Take your doses at the same time (i.e. with the same meals) every day
- Remember to refill your prescription. Place a reminder note on your calendar a week before the medicine is due to run out

Get support

- Tell a friend or partner who will help encourage your weight loss goals
- Join a group either in person or on line to help you stay encouraged and reminded of your goals

Use helpful tools

- Put a reminder note on your refrigerator, phone, medicine cabinet or bathroom mirror
- Set up a digital alarm on your computer or phone's calendar
- Track your progress by keeping a weight, food and exercise diary



People who track their food intake and physical activity – whether it is with pencil and paper, a computer programme, or an app on their phone – tend to be more successful with their weight loss programme than those who do not.

At the end of each week, give yourself a score of 0, 1 or 2 points for each item:

1 = A little

2=Yes

Then, tally the list to determine your total score for the week.



For further information please visit:
www.consilienthealth.ie and www.mysimba.ie

DIET/ EXERCISE CHECK LIST

EXERCISE CHECKLIST – this week did you...

Week

	1	2	3	4
Exercise for at least 30 mins most days of the week?				
Try to avoid watching television?				
Try a new or different physical activity?				
Use a tactic to reduce your stress?				
Tend to choose to take the stairs instead of an elevator or escalator?				
Try to walk or cycle, instead of drive or take the bus?				
Track your exercise in a journal/chart/app?				
Tend to follow your exercise programme?				

DIET CHECKLIST – this week did you...

Week

	1	2	3	4
Tend to choose vegetables and fruits as a snack?				
Track what you ate in a journal/chart/app?				
Try to plan your meals ahead of time?				
Tend to choose water over higher calorie beverages?				
Tend to avoid fast food and/or restaurant food?				
Tend to choose lean cuts of meat over higher fat cuts?				
Feel that you had your eating habits under control?				
Tend to follow your eating plan?				

0

= Not at all

1

= A little

2

= Yes

TOTAL SCORE

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For further information please visit:
www.mysimba.ie and www.consilienthealth.ie

REPORTING OF SIDE EFFECTS:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Malta: Please report any side effects or suspected adverse events to the Malta Medicines Authority via <http://medicinesauthority.gov.mt/adrportal> or Vivian Corporation Ltd. via pv@viviancorp.com.

Ireland: Please report any side effects or suspected adverse events to HPRA pharmacovigilance via www.hpra.ie. Click on *"I want to report an Issue"* and then click on *"Human medicines adverse events reports"* or Consilient Health via drugsafety@consilienthealth.com.

Adverse events should also be reported to **Orexigen: +353 1800 849 099** or CurraX.MI@primevigilance.com

Consilient Health

Block 2A Richview Office Park, Clonskeagh, Dublin 14, Ireland.
Tel: +353 1 205 7760 | www.consilienthealth.ie

Vivian

The Hub, Troubridge Street, Marsa, MRS1113, Malta.
Email: info@viviancorp.com

MARKETING AUTHORISATION HOLDER
Orexigen Therapeutics Ireland Limited
9-10 Fenian Street, Dublin 2,
D02 RX24, Ireland
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