Citidaron® Prescribing Fact Sheet

Please refer to full Summary of Product Characteristics before prescribing. Click here for SmPC
Please refer to back page For Prescribing Information and Adverse Event reporting information

A summary guide for Healthcare Professionals

About Citidaron®:

- The active ingredient is called cytisinicline (previously used name: cytisine), a plant alkaloid, and a partial agonist of the α4β2 nicotinic acetylcholine receptor that allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms.
- Citidaron® does not contain nicotine.
- Citidaron® is a Prescription Only Medicine; prescribed as a 25-day treatment course.
- One pack of Citidaron contains 100 tablets (2 blister packs of 50 tablets), which is sufficient for the complete, 25-day treatment course.

Indication:

Citidaron® is indicated for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking. The treatment goal is the permanent cessation of the nicotine-containing products use.[1]

Recommended Population:

Citidaron® should be taken only by those aged 18–65 years with a serious intention of weaning off nicotine.

Take orally with a suitable amount of water. Smoking should be stopped no later than on the 5th day of treatment. In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months.[1]

DOSAGE	Days of treatment	Recommended dosing	Maximum daily dose
	From the 1st to the 3rd day	1 tablet every 2 hours	6 tablets
	From the 4th to the 12th day	1 tablet every 2.5 hours	5 tablets
	From the 13th to the 16th day	1 tablet every 3 hours	4 tablets
	From the 17th to the 20th day	1 tablet every 5 hours	3 tablets
	From the 21st to the 25th day	1-2 tablets a day	up to 2 tablets

Special Populations:

Citidaron® is not recommended in the following patient populations as there is no or limited clinical information: renal or hepatic impairment; elderly (over 65 years); children (under 18 years).

Contraindications:

Hypersensitivity to the active substance or to any of the excipients (See SPC), unstable angina, history of recent myocardial infarction, clinically significant arrhythmias, history of recent stroke, pregnancy and breastfeeding.

Pregnancy & Breastfeeding:

Contraindicated. Women of childbearing potential must use highly effective contraception while taking Citidaron. Women using systemically acting hormonal contraceptives should add a second barrier method.

Interactions:

Should not be used with anti-tuberculosis drugs.

Tolerability:

Clinical studies and previous experience indicate a good tolerability. Mild to moderate adverse reactions have usually been observed, most frequently concerning the gastrointestinal tract. The majority of adverse reactions occurred at the beginning of the therapy and resolved during treatment. Symptoms could also be the result of smoking cessation, rather than the use of drug product.[1]

Undesirable effects:[1]

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): difficulty in concentration, slow heart rate, abdominal distension, burning tongue, malaise.
Uncommon (≥1/1000 to <1/100): dyspnea.
See SPC for full list of Uncommon undesirable effects.

Special Warnings & Precautions:

Use with caution in: ischemic heart disease; heart failure; hypertension; atherosclerosis and other peripheral vascular diseases; gastric and duodenal ulcer; gastroesophageal reflux disease; hyperthyroidism; pheochromocytoma; diabetes; schizophrenia.
Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly.[1] *continued on page 2*

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Special Warnings & Precautions *continued*:

Patients should be aware that the simultaneous administration of Citidaron and smoking or use of products containing nicotine could lead to aggravated adverse reactions of nicotine.[1]

Polycyclic aromatic hydrocarbons in tobacco smoke induce metabolism of drugs metabolised by CYP1A2 (and possibly by CYP1A1). Stopping smoking may result in slower metabolism and a rise in blood levels of such drugs. Potentially clinically important if narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole. Plasma concentration of products metabolised in part by CYP1A2 e.g. imipramine, olanzapine, clomipramine and fluvoxamine may also increase on smoking cessation; data are lacking and clinical significance unknown. Limited data indicate the metabolism of flecainide and pentazocine may also be induced by smoking. Women of childbearing potential: see page 1.

Cytisinicline's safety and clinical considerations:

The use of cytisinicline for smoking cessation is well established, with clinical experience from over 50 years' use in Eastern Europe[2] and has been shown in randomised, placebo-controlled trials[3,4] real-world use[5,6] and trials comparing Nicotine Replacement Therapy (NRT)[7] and varenicline.[8,9]

NICE recognises cytisinicline in smoking cessation guidelines

As of February 2025, the National Institute for Health and Care Excellence (NICE) in the UK has included cytisinicline (previously used name cytisine) as a recommended pharmacotherapy for smoking cessation in its guidance on treating tobacco dependence[10].

Efficacy findings from the 2023 Cochrane review

A 2023 Cochrane review assessed cytisinicline's efficacy and safety, analysing multiple randomized controlled trials[11].

Key findings include:

- Cytisinicline was associated with a smoking cessation success rate of approximately 13%, compared to 6% in the control group at 6–12 months[11].
- Cytisinicline approximately doubles the likelihood of smoking cessation compared to placebo[11].
- Efficacy results from cytisinicline studies are broadly similar to those observed for varenicline in varenicline studies, based on indirect comparisons[11].
- Side effects are generally mild and transient, with gastrointestinal discomfort and sleep-related symptoms being the most commonly reported[11].

It is important to note that some studies in the Cochrane review utilized dosage regimens outside of the licensed dosing schedule.

For More Information And To Access Patient Support Materials

Visit the Consilient Health Citidaron® website
https://www.consilienthealth.ie/Citidaron

Scan the QR code to save your Primary Care Specialists contact details or get in touch directly:

Siobhan Maguire
North Dublin & Donegal

Gemma Fitzsimons
South Dublin, Waterford & Cork

Regina Brady
West of Ireland & Kerry

References:

1. Cytisinicline Summary of Product Characteristics (2025).
2. Prochaska JJ et al. BMJ 2013;347: f5198
3. West R et al N Engl J Med 2011;365:1193-2003;
4. Vinnikov, D et al J Smoking Cessation, 2008;3(1), 57–62;
5. Zatonski W et al Tobacco Control 2006;15:481–484;
6. Jiménez-Ruiz CA et al. Arch Bronconeumol. 2023 Apr;59(4):270-272
7. Walker N et al N Engl J Med 2014;371:2353-62
8. Courtney RJ et al JAMA 2021 326(1)56-64
9. Oreskovic T et al Nicotine Tob Res. 2023 Aug 19;25(9):1547-1555.
10. NICE. 2024 exceptional surveillance of tobacco: preventing uptake, promoting quitting and treating dependence (NICE guideline NG209) https://www.nice.org.uk/guidance/ng209/evidence. Accessed May 2025
11. Lindson N et al. Cochrane Database Syst Rev 2023;9:CD015226

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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 sufficient 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 significant 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):** difficulty 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 Office 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.