Consilient Health

FOR HEALTHCARE PROFESSIONALS IN IRELAND ONLY

FROM NICOTINE

Indicated for smoking cessation and the reduction of nicotine cravings in smokers who are willing to quit[1]

PRESCRIBING INFORMATION & ADVERSE EVENT REPORTING DETAILS CAN BE FOUND HERE

Citidaron® Cytisine

Nicotine-free. Fast. Effective. Available.

Introducing CITIDARON®

- CITIDARON® is indicated for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking[1]

- The treatment goal of CITIDARON® is the permanent cessation of the nicotine-containing products use[1]

  - A smoker is five times more likely to quit permanently if they commit to quitting for 28 days, receive support to change their behavior, and use stop-smoking medications[2]

  - Each attempt to quit smoking is vital, as every effort brings smokers one step closer to permanently overcoming this habit

Click **HERE** for information on prescribing

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Cytisine

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Why use CITIDARON®?

Pharmacological and electronic cigarette interventions for smoking cessation in adults: component network meta-analyses (Review)

Summary of findings: Lindson meta-analysis, smoking cessation at 6 months [3]

Component	Number of participants (studies) with data on component	Relative effect (95% credibility interval)	Anticipated absolute effect			Certainty of the evidence	Notes
			Without intervention	With intervention	Difference		
Varenicline	16,430 (67 RCTs)	OR 2.33 (2.02 to 2.68)	6 per 100	14 per 100 (12 to 16)	8 per 100 (6 to 10)	High	Prediction interval: 1.31 to 4.11
Cytisine	**3848 (7 RCTs)**	**OR 2.21 (1.66 to 2.97)**	**6 per 100**	**13 per 100 (10 to 18)**	**7 per 100 (4 to 12)**	**High**	**Prediction interval: 1.19 to 4.22**
Nicotine patch	37,319 (105 RCTs)	OR 1.37 (1.20 to 1.56)	6 per 100	8 per 100 (7 to 9)	2 per 100 (1 to 3)	High	Prediction interval: 0.77 to 2.41
Fast acting nicotine replacement therapy	31,756 (120 RCTs)	OR 1.41 (1.29 to 1.55)	6 per 100	9 per 100 (8 to 9)	3 per 100 (2 to 3)	High	Prediction interval: 0.81 to 2.49
Nicotine e-cigarette	3828 (16 RCTs)	OR 2.37 (1.73 to 3.24)	6 per 100	14 per 100 (10 to 19)	8 per 100 (4 to 13)	High	Prediction interval: 1.26 to 4.48
Non-nicotine /placebo e-cigarette	1094 (8 RCTs)	OR 1.16 (0.74 to 1.80)	6 per 100	7 per 100 (4 to 11)	1 per 100 (–2 to 5)	Low	Prediction interval: 0.57 to 2.36
Bupropion	14,759 (71 RCTs)	OR 1.43 (1.26 to 1.62)	6 per 100	9 per 100 (8 to 10)	3 per 100 (2 to 4)	High	Prediction interval: 0.81 to 2.52
Nortriptyline	1290 (10 RCTs)	OR 1.35 (1.02 to 1.81)	6 per 100	8 per 100 (6 to 11)	2 per 100 (0 to 5)	Moderate	Prediction interval: 0.72 to 2.55
Nicotine tapering	33,156 (111 RCTs)	OR 1.14 (1.00 to 1.29)	6 per 100	7 per 100 (6 to 8)	1 per 100 (0 to 2)	Low	Prediction interval: 0.64 to 2.00

RCT: randomised controlled trial; OR: odds ratio.

Please note some of the studies referenced in the Cochrane report used dosage regimes outside the licensed dosage regime

- In a recent Cochrane review, the chances of quitting smoking with cytisine are over twice as high, with a **success rate of 13%**, compared to a 6% chance with control predominantly at 6 months to 12 months[3]
- Cytisine exhibited a low frequency of serious adverse events (2%) during clinical trials, suggesting it is generally well-tolerated by patients[3]
- The high-certainty evidence from the study underlines a well-defined safety profile for cytisine, making it a predictable option for smoking cessation[3]

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How to use CITIDARON®

CITIDARON® is supplied in a packet of 100 tablets and one packet of CITIDARON® is sufficient for a complete 25-day course of therapy

- CITIDARON® should be taken as per the recommendations below:[1]

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

Smoking should be stopped **no later than on the 5th day of treatment**

Smoking should not be continued during treatment as this may aggravate adverse reactions

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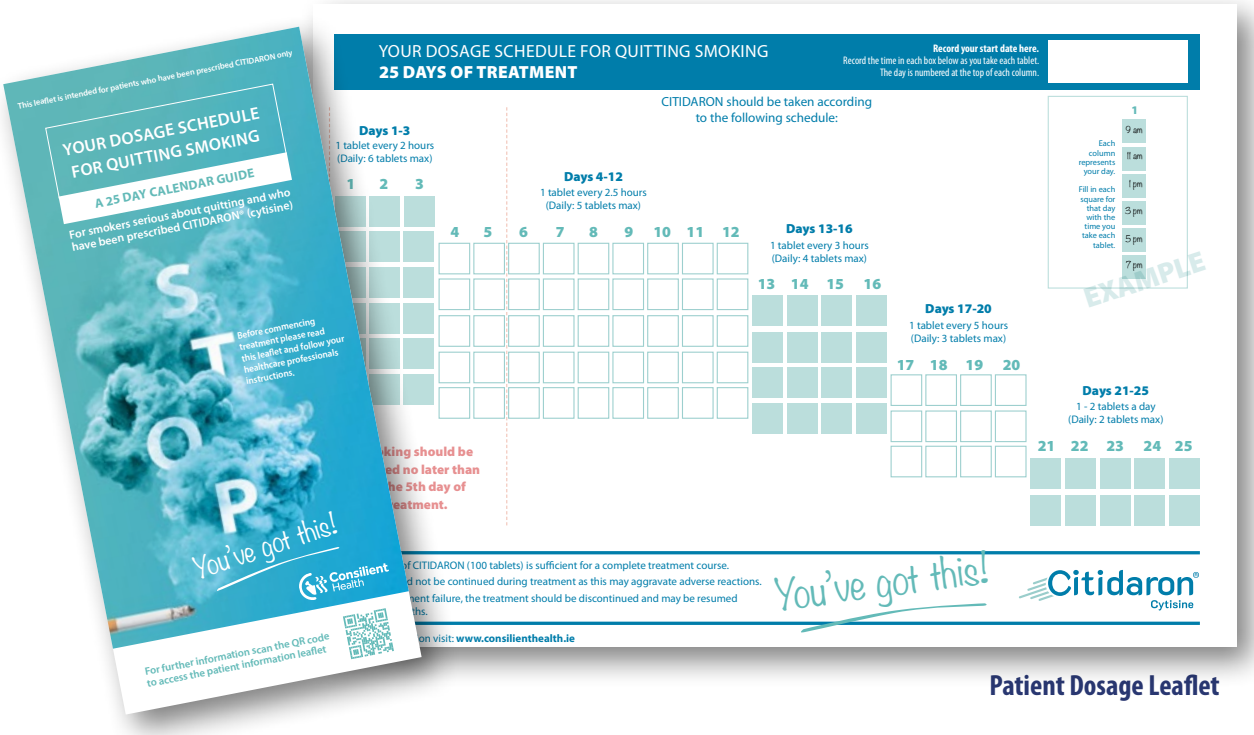
CITIDARON® dosage schedule[1]



Patient Dosage Leaflet

Additional HCP support and CITIDARON® Dosing Guide and Patient Leaflet is available to download **HERE**

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1 PACK = FULL TREATMENT

ONLY 25 DAYS TREATMENT

DOES NOT CONTAIN NICOTINE

REDUCES WITHDRAWAL SYMPTOMS

WELL ESTABLISHED TOLERABILITY PROFILE

CLINICALLY PROVEN EFFICACY

References

1. CITIDARON® SmPC (2023) Available at: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA22714-001-001_02082022144903.pdf [Accessed: December 2023]

2. HSE Quit smoking 2023 Available at https://www2.hse.ie/living-well/quit-smoking/get-help-to-quit/we-can-quit/#:~:text=You%20are%205%20times%20more,use%20stop%20smoking%20medicines [Accessed December 2023]

3. Lindson N, Theodoulou A, Ordóñez-Mena JM et al. Cochr Data Syst Rev 2023, Issue 9. Art. No.: CD015226.

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

Product name: Cytisine 1.5mg tablets Composition: 1.5mg of 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. **Breast-feeding:** 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: €113.87 (Net Wholesale Price).
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(2) Date of preparation: December 2023

Healthcare professionals are asked to report any suspected adverse reactions. To report an adverse event or a product complaint about a Consilient Health medicine, please contact Consilient Health at drugsafety@consilienthealth.com or 012057766
Adverse events and product complaints may also be reported to the Health Products Regulatory Authority. Reporting form and information can be found at www.hpra.ie then click on "report an issue".

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