

FREE



FROM NICOTINE

Citidaron[®]
Cytisine

Nicotine-free. Fast. Effective. Available.

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



Adverse Events / Product Complaints or for
Pharmacovigilance or Medical enquiries please contact:
E: drugsafety@consilienthealth.com
T: (01) 205 7766
All other queries: (01) 205 7760

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 <http://www.hpra.ie> then click on "report an issue".

STOP

THE BURDEN OF SMOKING ON HEALTH, HEALTHCARE AND SOCIETY IS CONSIDERABLE

- Globally, 1.3 billion people use tobacco. Of these, tobacco use kills more than 8 million people worldwide every year¹



- Across Ireland in 2022, 18% of the population were estimated to smoke, 16% smoked daily and 2% smoked occasionally²

- 20% of men and 17% of women smoke²

- Although there was a steady decline in the prevalence of smoking in Ireland from 23% in 2015 to 17% in 2019, this rate has now increased slightly²



- In 2019, approximately 4,500 deaths were attributed to smoking²

- Smoking and its effects place a large pressure on healthcare resources. In 2019, 44,000 hospitalisations were estimated to be attributed to smoking²



Smoking contributed to:

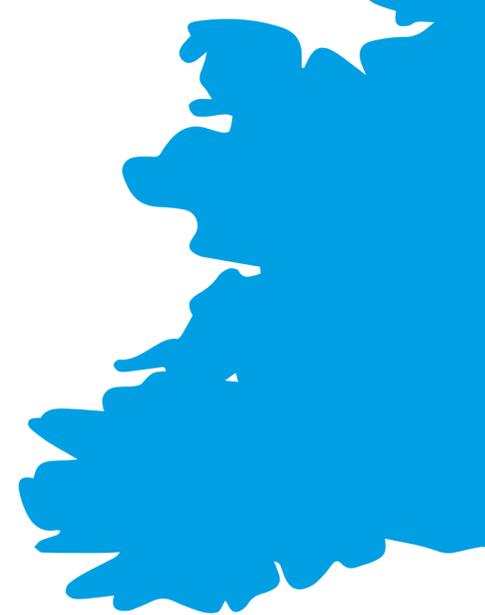
- 20% of respiratory disease hospitalisations
- 10% of circulatory disease hospitalisations
- 12% of cancer hospitalisations in 2019²



- In 2013, the estimated cost to the healthcare system of smoking was over €460 million, the cost of lost productivity was over €1 billion, and the cost of loss of welfare was over €9 billion³

SMOKING CESSATION IS A PRIORITY IN IRELAND

- The Department of Health (DOH) in Ireland have set a target to obtain a 'smoke-free' Ireland by 2025, which is a smoking prevalence of less than 5%⁴
- Support for a 'smoke-free' Ireland is high amongst the Irish population⁵
- Enhancing the progress of smoking cessation services nationally is critical in achieving a 'smoke free' Ireland⁶



References

1. World Health Organization. Tobacco Factsheet. Available at <https://www.who.int/news-room/fact-sheets/detail/tobacco>. Accessed November 2023.
2. HSE Tobacco Free Ireland Programme. The state of tobacco control in Ireland 2022. Available at <https://www.hse.ie/eng/about/who/tobaccocontrol/news/state-of-tobacco-control-report-2022.pdf>. Accessed November 2023.
3. ICF International. An assessment of the economic cost of smoking in Ireland. Available at <https://assets.gov.ie/34808/8b5d52eaa4447419f38b447733d02b9.pdf>. Accessed November 2023.
4. Department of Health. Tobacco Free Ireland Annual Report 2021. Available at <https://www.gov.ie/en/publication/eaef0-tobacco-free-ireland-2021-annual-report/#:~:text=Tobacco%20Free%20Ireland%20is%20Ireland's,and%20the%20denormalisation%20of%20smoking>. Accessed November 2023.
5. Bringing the tobacco epidemic to an End: Public views on Tobacco Endgame in Ireland May 2022. Available at <https://www.hse.ie/eng/about/who/tobaccocontrol/news/tobacco-endgame-report-2022.pdf>. Accessed November 2023.
6. Stop Smoking National Clinical Guideline No. 28, 2022. Available at <https://www.gov.ie/en/publication/4828b-stop-smoking/>. Accessed November 2023.



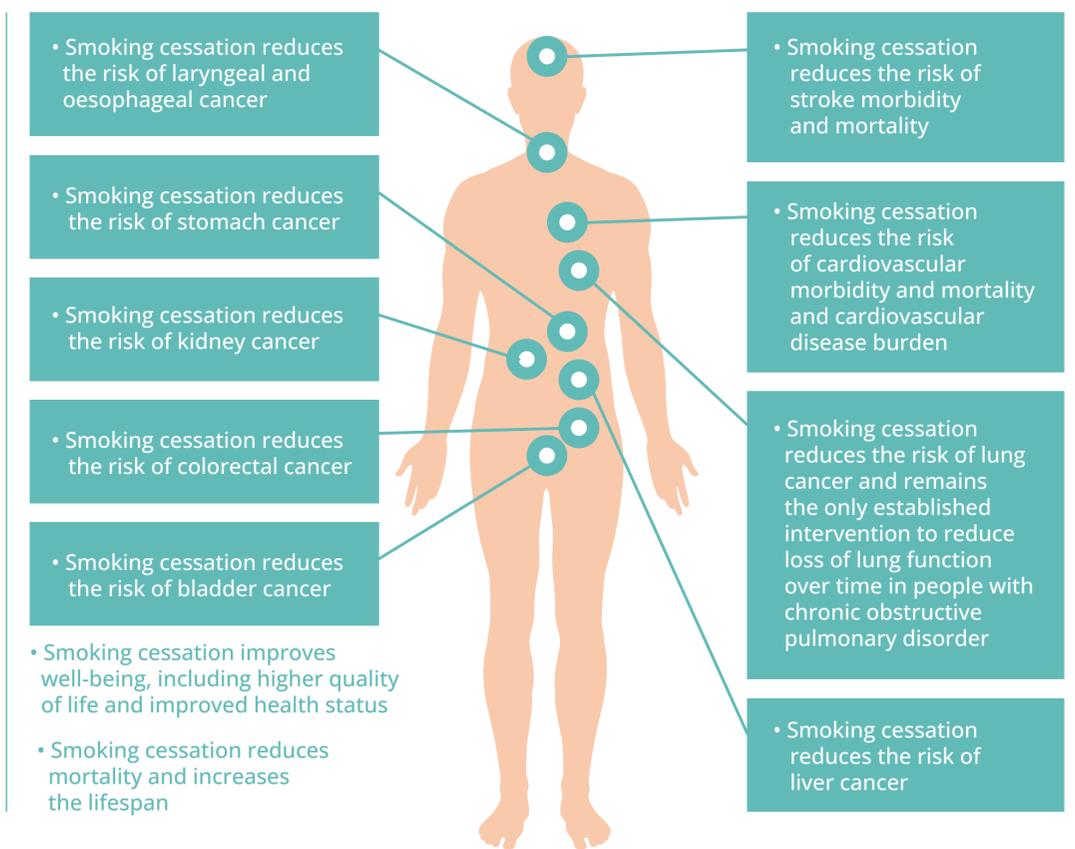
SMOKERS EXPERIENCE A RANGE OF BENEFITS WHEN THEY QUIT SMOKING

When people give up smoking, they experience a range of short, medium-term health benefits: ¹

- **In a few days**, their heart rate drops, their sense of smell and taste improves, and their blood levels of carbon monoxide and oxygen return to normal
- **In a few weeks**, their risk of sudden death from a heart attack is reduced, their lung function improves, and they are less short of breath
- **In a few months**, their symptoms of chronic bronchitis improve, and they are at reduced risk of ulcers ¹

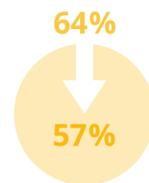


THE BENEFITS OF SMOKING CESSATION OCCUR THROUGHOUT THE BODY ²



QUITTING SMOKING IS DIFFICULT AND PEOPLE WHO WANT TO QUIT NEED YOUR HELP

- Over recent years, the number of smokers who have reported a positive intention to quit has fallen from 64% in 2015 to 57% in 2021³



- Across the same period, the proportion of smokers who made an attempt to quit in a given year decreased from 53% to 46%³

- It is important that people who smoke keep trying to quit. It may take more than 30 unsuccessful attempts before they succeed in stopping smoking⁴ and so the existence of a wide range of available smoking cessation services across Ireland may help people to continue to try to quit



References

1. NHS Inform. Benefits of stopping smoking. Available at <https://www.nhsinform.scot/healthy-living/stopping-smoking/reasons-to-stop/benefits-of-stopping-smoking/>. Accessed November 2023.
2. Stop Smoking National Clinical Guideline No. 28, 2022. Available at: <https://www.gov.ie/en/publication/4828b-stop-smoking/>. Accessed November 2023.
3. HSE Tobacco Free Ireland Programme. The state of tobacco control in Ireland 2022. Available at: <https://www.hse.ie/eng/about/who/tobaccocontrol/news/state-of-tobacco-control-report-2022.pdf>. Accessed November 2023.
4. Chaiton M, Diemert L, Cohen JE, et al. Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers. *BMJ Open* 2016;6:e011045.



Introducing CITIDARON®	How CITIDARON® works	When to use CITIDARON®?
Why use CITIDARON®?	How to use CITIDARON®?	CITIDARON® prescribing considerations

INTRODUCING CITIDARON®

CITIDARON® is indicated for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking¹

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

- Research shows that smokers who get help and use proven methods like **behavioural support and medications are more likely to successfully quit**²
- Each attempt to quit smoking is vital, as every effort brings smokers **one step closer to permanently overcoming this habit.**
- CITIDARON® is a **25 day treatment course**¹
- CITIDARON® **does not contain nicotine** and has a favourable tolerability profile



References

1. Cytisine Summary of Product Characteristics, Consilient Health 2023.

2. HTA of smoking cessation interventions HSE (2017) Available at: <https://www.hiqa.ie/reports-and-publications/health-technology-assessment/hta-smoking-cessation-interventions> [Accessed November 2023].



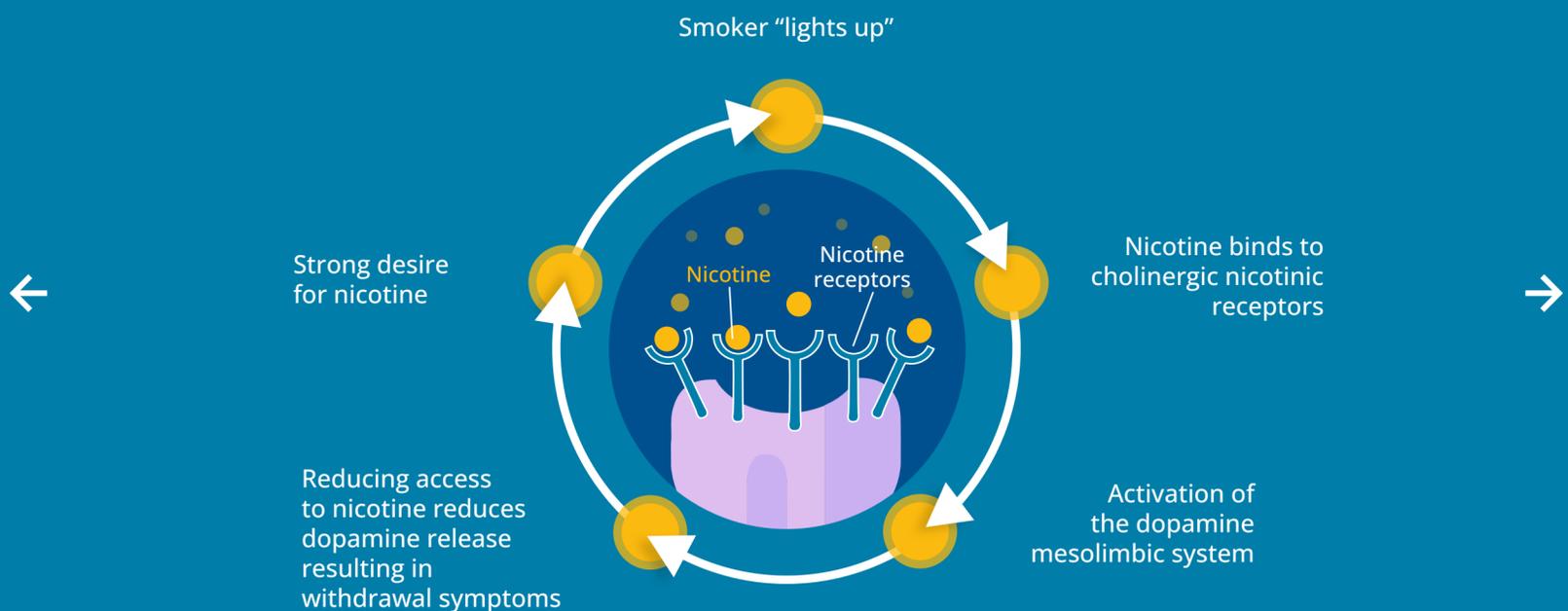
Introducing CITIDARON [®]	How CITIDARON[®] works	When to use CITIDARON [®] ?
Why use CITIDARON [®] ?	How to use CITIDARON [®] ?	CITIDARON[®] prescribing considerations

HOW CITIDARON[®] WORKS

- CITIDARON[®] is a **partial agonist** of the $\alpha 4\beta 2$ nicotinic acetylcholine receptor¹
- CITIDARON[®] **competes with nicotine** for the same receptors and gradually displaces nicotine due to its stronger binding. It has lower ability to stimulate nicotinic receptors¹
- It **prevents nicotine-dependent full activation** of the mesolimbic dopamine system and moderately increases level of dopamine in the brain. **This alleviates the central symptoms of nicotine withdrawal**¹
- In the peripheral nervous system, it **influences breathing, catecholamine secretion, and blood pressure** and helps mitigate peripheral symptoms of nicotine withdrawal¹



MECHANISM OF ACTION OF NICOTINE DEPENDENCE





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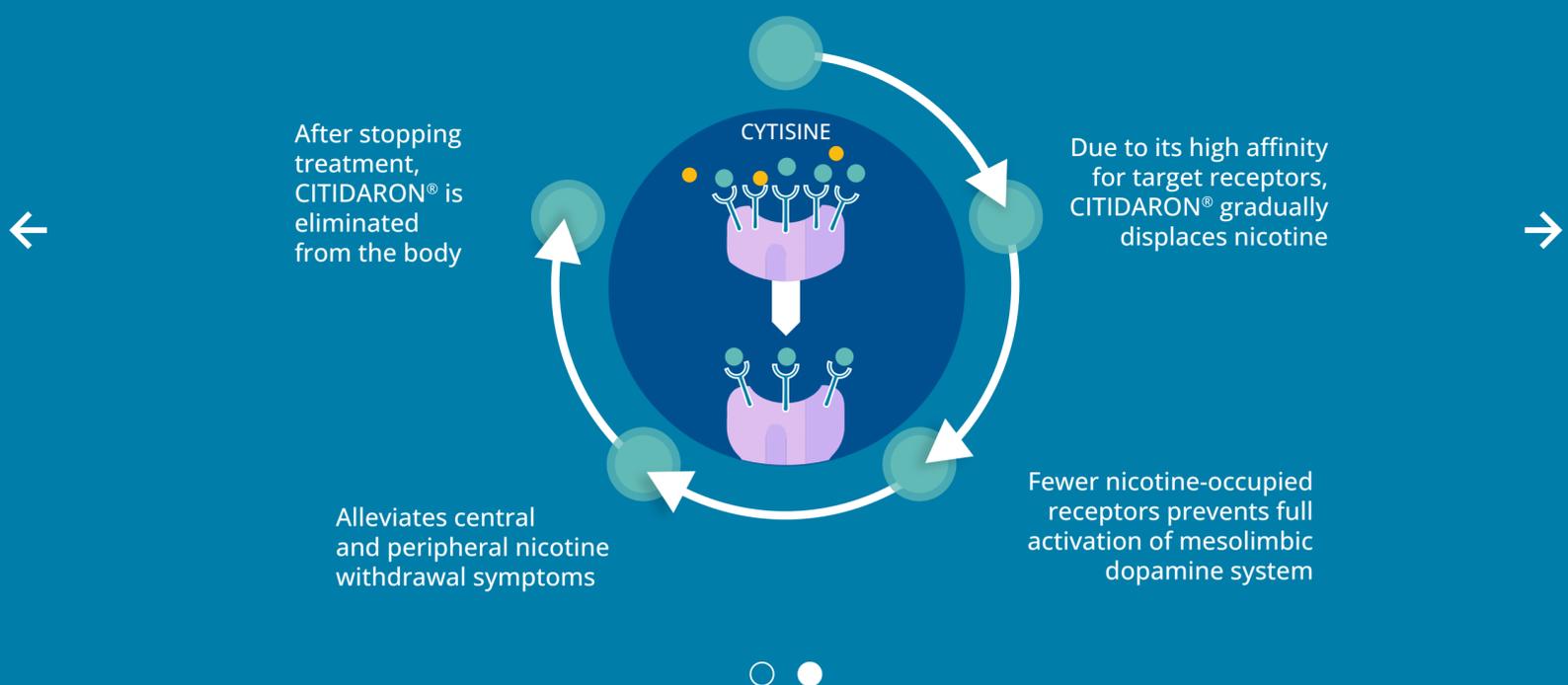
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MECHANISM OF ACTION OF CITIDARON[®]

CITIDARON[®] competes with nicotine for the same nicotinic receptors



Reference
1. CITIDARON[®] Summary of Product Characteristics, Consilient Health 2023.



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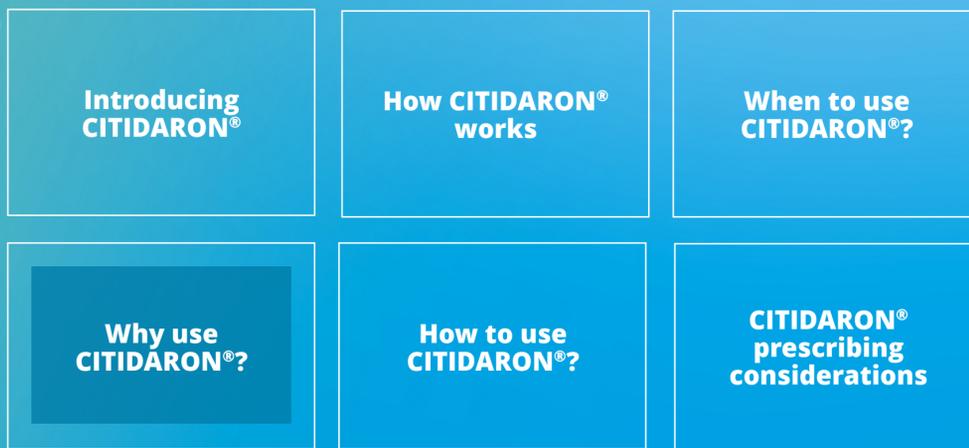
WHEN TO USE CITIDARON[®]?

- CITIDARON[®] should be used in smokers **who are willing to stop smoking**¹
- From the outset of treatment, **the goal should be the permanent cessation of the nicotine-containing products use**¹
- CITIDARON[®] can be prescribed as a **first-line treatment** option for smoking cessation
- Current treatment options have therapy cycles that **range between 7 and 12 weeks**. This is a **significant time burden** and may be a barrier to their use in certain patients^{2,3}
- CITIDARON[®] offers patients a **25-day treatment period**¹ which patients may view as a manageable commitment when commencing their quitting journey



References

1. Citidaron Summary of Product Characteristics, Consilient Health 2023.
2. Zyban (bupropion) Summary of Product Characteristics. Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-017-001_03102023123549.pdf. Accessed November 2023.
3. Champix (varenicline) Summary of Product Characteristics. Available at https://www.ema.europa.eu/en/documents/product-information/champix-epar-product-information_en.pdf. Accessed November 2023.



WHY USE CITIDARON®?

- The active ingredient of CITIDARON® (cytisine) has been used as a smoking cessation treatment in Eastern Europe for decades¹
- A meta-analysis that included 7 studies of cytisine published between 1968 and 2011 showed that cytisine was an effective treatment for smoking cessation (risk ratio = 1.59, confidence interval 1.43 to 1.75)²



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** during clinical trials, suggesting it is **generally well-tolerated by patients.**
- The high-certainty evidence from the study underlines a **well-defined safety profile for Cytisine,** making it a predictable option for smoking cessation.

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

Summary of findings: Lindson meta-analysis, smoking cessation at 6 months³

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

References

1. Karnieg T, Wang X. CMAJ 2018;190(19):E596.
2. Hajek P, McRobbie H, Myers K. Thorax 2013;68:1037-1042.
3. Lindson N, Theodoulou A, Ordóñez-Mena JM et al. Cochr Data Syst Rev 2023, Issue 9. Art. No.: CD015226.



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HOW TO USE CITIDARON[®]?

- CITIDARON[®] is administered over a 25-day complete treatment course, with one pack containing 100 tablets sufficient for the entire course¹



YOUR DOSAGE SCHEDULE FOR QUITTING SMOKING
25 DAYS OF TREATMENT

Record your start date here. Record the time in each box below as you take each tablet. The day is numbered at the top of each column.

CITIDARON should be taken according to the following schedule:

Days 1-3 1 tablet every 2 hours (Daily: 6 tablets max)			Days 4-12 1 tablet every 2.5 hours (Daily: 5 tablets max)									Days 13-16 1 tablet every 3 hours (Daily: 4 tablets max)				Days 17-20 1 tablet every 5 hours (Daily: 3 tablets max)				Days 21-25 1 - 2 tablets a day (Daily: 2 tablets max)				
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Each column represents your day. Fill in each square for that day with the time you take each tablet.

EXAMPLE: 9 am, 11 am, 1 pm, 3 pm, 5 pm, 7 pm

• One package of CITIDARON (100 tablets) is sufficient for a complete treatment course.
 • Smoking should not be continued during treatment as this may aggravate adverse reactions.
 • In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months.

For more information visit: www.consilienthealth.ie

You've got this!

Citidaron[®]
Cytisine



[Downloadable version](#)

Reference
1. CITIDARON[®] Summary of Product Characteristics, Consilient Health 2023.



CITIDARON® PRESCRIBING CONSIDERATIONS

CITIDARON® INDICATION ¹

- CITIDARON® is indicated for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking
- The treatment goal of CITIDARON® is the permanent cessation of the nicotine-containing products use
- Please refer to the full [Summary of Product Characteristics](#) before prescribing CITIDARON®

CONTRAINDICATIONS ¹

CITIDARON® is contraindicated in patients with:

- Hypersensitivity to the active substance or any of excipients
- Unstable angina
- A history of recent myocardial infarction
- Clinically significant arrhythmia
- A history of recent stroke
- Pregnancy or breastfeeding

CITIDARON® should be used with caution in patients with:

- Ischaemic heart disease
- Heart failure
- Hypertension
- Pheochromocytoma
- Atherosclerosis and other peripheral vascular disease
- Gastric and duodenal ulcer
- Gastroesophageal reflux disease
- Hyperthyroidism
- Diabetes
- Schizophrenia

- Depressed mood may be a symptom of nicotine withdrawal. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with and without treatment
- 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
- Women of childbearing potential must use highly effective contraception while taking CITIDARON®. It is currently unknown whether CITIDARON® may reduce the effectiveness of systemically acting hormonal contraceptives, and therefore women using systemically acting hormonal contraceptives should add a second barrier method
- There is no clinical experience of CITIDARON® in patients with renal or hepatic impairment, therefore CITIDARON® is not recommended for use in this patient population
- CITIDARON® is not recommended for use in patients <18 years and patients >65 years

CITIDARON® TOLERABILITY ¹

- Mild to moderate adverse reactions have been observed with the use of CITIDARON®, most frequently concerning the gastrointestinal tract.
- Clinical trials and prior experience indicate that the majority of adverse reactions occurred at the beginning of CITIDARON® therapy and resolved during treatment.

The following more frequently noted adverse events were observed in clinical trials.

Adverse event class	Very common (≥1/10)	Common (≥1/100 to <1/10)
Metabolism and nutrition disorders	Change in appetite (mainly increase), weight gain	
Nervous system disorders	Dizziness, irritability, mood changes, anxiety, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches	Difficulty in concentration
Cardiac disorders	Tachycardia	Slow heart rate
Vascular disorders	Hypertension	
Gastrointestinal disorders	Dry mouth, diarrhoea, nausea, changes flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen)	Abdominal distension, burning tongue
Skin and subcutaneous tissue disorders	Rash	
Musculoskeletal and connective tissue disorders	Myalgia	
General disorders and administration site conditions	Fatigue	Malaise

Reference
1. CITIDARON® Summary of Product Characteristics, Consilient Health 2023.

 **PRESCRIBING INFORMATION**

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 ($\geq 1/10$): 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 ($\geq 1/100$ 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

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