



CYTISINE PRESCRIBING FACT SHEET

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For Prescribing Information and Adverse Event reporting information [click here](#)

A summary guide for HCPs

ABOUT CYTISINE:

- CYTISINE, a plant-derived alkaloid, is a partial nicotine receptor agonist that helps stop smoking by reducing cravings and withdrawal symptoms.¹ CYTISINE does not contain nicotine.
- CYTISINE (also known as cytisinicline) is a Prescription Only Medicine; that has a treatment course of just 25 days.
- One pack of CYTISINE contains 100 tablets (2 strips of 50 tablets), which is sufficient for the complete, 25-day treatment course.
- CYTISINE has now been included in NICE guidelines as a recommended treatment option.²

INDICATION:

CYTISINE 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:

CYTISINE 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	to 2 tablets

SPECIAL POPULATIONS:

CYTISINE 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 CYTISINE. 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 ($\geq 1/10$): 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.
Uncommon ($\geq 1/1000$ 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*

Cytisine
Consilient Health

A non-nicotine smoking cessation
option with a 25-day treatment course



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SPECIAL WARNINGS & PRECAUTIONS *continued*:

Patients should be aware that the simultaneous administration of CYTISINE 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*.

CLINICAL EVIDENCE FOR CYTISINE:

The use of CYTISINE for smoking cessation is well established, with clinical experience from over 50 years' use in Eastern Europe³ and has been shown in randomised, placebo-controlled trials^{4,5} real-world use^{6,7} and trials comparing Nicotine Replacement Therapy (NRT)⁸ and varenicline^{9,10}. For more information on clinical trial data for CYTISINE, see the Resources section of the quitsmokingsupport website [here](#)

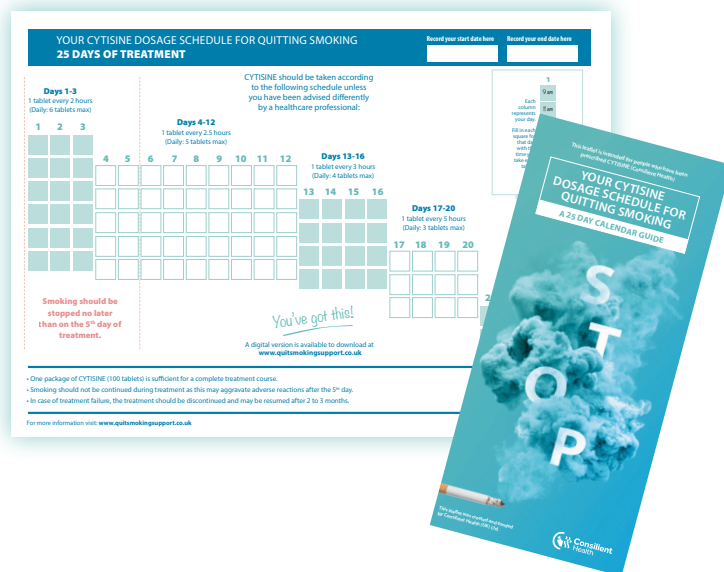
Based on a review of the clinical and cost-effectiveness evidence, CYTISINE (cytisinicline) was added as a first line treatment option for smoking cessation in NICE guidelines NG209, updated February 2025. CYTISINE is included as one of the treatment options that, "when combined with behavioural support, are more likely to result in them successfully stopping smoking".² A national Patient Group Direction (PGD) template for the supply of cytisinicline (CYTISINE) tablets as part of a local tobacco dependence treatment service has been issued by the Specialist Pharmacy Service.¹¹ CYTISINE is also a recommended treatment option in Wales.¹²



FOR MORE INFORMATION AND TO ACCESS PATIENT SUPPORT MATERIALS

Visit the Consilient Health CYTISINE website

<https://www.quitsmokingsupport.co.uk/>



Or contact the Consilient Health team:

Lesley Tew

ltew@consilienthealth.com

Medical Information drugsafety@consilienthealth.com

Other useful resources regarding CYTISINE and smoking cessation

NICE <https://www.nice.org.uk/guidance/ng209/>

AMWSG <https://awttc.nhs.wales/accessing-medicines/medicine-recommendations/cytisinicline-cytisine/>

NCSCT <https://www.ncsct.co.uk/publications/category/cytisine>

BTS Medical Management of inpatients with tobacco dependency <https://www.brit-thoracic.org.uk/quality-improvement/clinical-statements/medical-management-of-inpatients-with-tobacco-dependency/>

Patient Group Direction (SPS) <https://www.sps.nhs.uk/articles/cytisinicline-for-smoking-cessation/>

SPC <https://www.medicines.org.uk/emc/product/15789/>

For Prescribing Information, please scan the QR code. Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE UK or drugsafety@consilienthealth.com



References:

1. Cytisine Summary of Product Characteristics.
2. NICE Guideline [NG209] Tobacco: preventing uptake, promoting quitting and treating dependence. Last updated: 04 February 2025 <https://www.nice.org.uk/guidance/ng209>
3. Prochaska JJ et al. BMJ 2013;347: f5198
4. West R et al N Engl J Med 2011;365:1193-2003;
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6. Zatonski W et al Tobacco Control 2006;15:481-484;
7. Jiménez-Ruiz CA et al. Arch Bronconeumol. 2023 Apr;59(4):270-272
8. Walker N et al N Engl J Med 2014;371:2353-62
9. Courtney RJ et al JAMA 2021 326(1):56-64
10. Oreskovic T et al Nicotine Tob Res. 2023 Aug 19;25(9):1547-1555.
11. Specialist Pharmacy Service. Cytisinicline for smoking cessation (5 February 2025). <https://www.sps.nhs.uk/articles/cytisinicline-for-smoking-cessation/>
12. All Wales Therapeutics and Toxicology Centre. <https://awttc.nhs.wales/accessing-medicines/medicine-recommendations/cytisinicline-cytisine/>