



# 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 alkaloid, is a partial agonist of the  $\alpha_4\beta_2$  nicotinic acetylcholine receptor that allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms. CYTISINE does not contain nicotine.
- CYTISINE (also known as cytisinicline) is a Prescription Only Medicine; prescribed as a 25-day treatment course.
- One pack of CYTISINE contains 100 tablets (2 strips of 50 tablets), which is sufficient for the complete, 25-day treatment course. CYTISINE is available in the UK now via all main wholesalers.

### 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.<sup>1</sup>

### 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.<sup>1</sup>

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.<sup>1</sup>

### Undesirable effects:<sup>1</sup>

**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.<sup>1</sup> *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.<sup>1</sup>

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 Europe<sup>2</sup> and has been shown in randomised, placebo-controlled trials<sup>3,4</sup> real-world use<sup>5,6</sup> and trials comparing Nicotine Replacement Therapy (NRT)<sup>7</sup> and varenicline.<sup>8,9</sup> For more information on clinical trial data for CYTISINE, see Resources section of the quitsmokingsupport website [here](#)

Following its launch, NICE published an exception review of the evidence for CYTISINE in February 2024, which concluded that "cytisine should be listed in the medicinally licensed product recommendations as an option for people who smoke."<sup>10</sup>

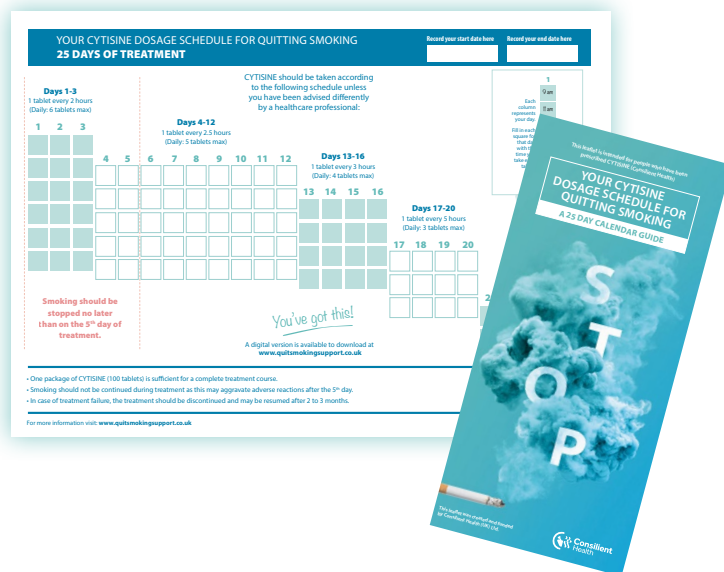
The All Wales Medicine Strategy Group (AWMSG) published the following guidance in July 2024: "Cytisinicline (cytisine) is recommended as an option for use within NHS Wales for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking."<sup>11</sup>



## 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:

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## Other useful resources regarding CYTISINE and smoking cessation

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

**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/>

**BNF** <https://bnf.nice.org.uk/drugs/cytisinicline/>

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

You can also access via scanning the QR code



## References:

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7. Walker N et al N Engl J Med 2014;371:2353-62
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11. All Wales Therapeutics and Toxicology Centre. Medicines recommendations. Cytisinicline / Cytisine. <https://awttc.nhs.wales/accessing-medicines/medicine-recommendations/cytisinicline-cytisine/> Accessed Oct 2024