

Cytisinicline (Cytisine®) 1.5mg tablets for smoking cessation – Factsheet for Prescribers

Medicine Summary:

Cytisinicline is licensed for smoking cessation and reduction of nicotine cravings in those aged 18 – 65 years old who are willing to stop smoking. The treatment goal of Cytisinicline is the permanent cessation of the use of nicotine-containing products. The use of Cytisinicline allows for a gradual reduction of nicotine dependence by relieving craving and withdrawal symptoms.

Dosing:

Each tablet contains 1.5mg of Cytisinicline. One pack of Cytisinicline contains 100 tablets which is a complete treatment course (25 days). Cytisinicline should be taken with water according to the following schedule with the quit date no later than the fifth day of treatment:

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	2 tablets

Safety

Cytisinicline has been used in Europe by several million people who smoke, mostly without prescription, and to date there has been no evidence of any serious adverse events.

A lack of clinical experience or safety data means that Cytisinicline is not recommended for patients:

- with renal (kidney) impairment
- with hepatic (liver) impairment
- over 65 years of age
- under 18 years of age

Contraindications

Cytisinicline should not be used if patients have:

- hypersensitivity to Cytisinicline
- hypersensitivity to any of the excipients (non-active ingredients): mannitol, microcrystalline cellulose, magnesium stearate, glycerol dibehenate and hypromellose

- unstable angina
- had recent myocardial infarction
- clinically significant arrhythmias
- had a recent stroke
- should not be used with anti-tuberculosis drugs
- pregnant or breastfeeding

Women of childbearing age using hormonal contraception should add a secondary barrier method whilst taking Cytisinicline as its impact on the effectiveness of oral contraceptives is not known.

Cautions

Cytisinicline should be taken with caution if patients have:

- ischemic heart disease
- heart failure
- hypertension (high blood pressure)
- pheochromocytoma (tumor in the adrenal glands)
- atherosclerosis (thickening or hardening of the arteries) and other peripheral vascular diseases
- gastric and duodenal ulcer
- gastroesophageal reflux disease
- hyperthyroidism (overactive thyroid)
- diabetes
- schizophrenia

Side effects by frequency

Very common (may affect more than 1 user in 10): change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, hypertension, dry mouth, diarrhoea, rash, fatigue, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, tachycardia, nausea, alters some flavours, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen), muscle pain.

Common (may affect 1 to 10 users in 100): difficulty in concentration, slow heart rate, abdominal distension, burning tongue, malaise.

Uncommon (affects 1 to 10 users in 1,000): feeling of heaviness in the head, decreased libido, lacrimation (abnormal or excessive secretion of tears), dyspnea (shortness of breath), increased sputum (phlegm), excessive salivation, sweating, decreased elasticity of the skin, tiredness, increase in serum transaminase levels

For further information, see full prescriber guide developed by the National Centre for Smoking Cessation and Training - [NCSCT A5 cytisine v8](#)