Package leaflet: Information for the user

Cytisinicline 1.5 mg tablets

cytisinicline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Cytisinicline is and what it is used for

Smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.
The treatment goal of Cytisinicline is the permanent cessation of the nicotine-containing products use.

The use of Cytisinicline allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms.

2. What you need to know before you use Cytisinicline

Do not use Cytisinicline:
- if you are allergic to cytisinicline (previously used name: cytisine) or any of the other ingredients of this medicine (listed in section 6).
- if you have unstable angina,
- if you have a history of recent myocardial infarction,
- if you have clinically significant cardiac arrhythmias,
- if you had stroke recently,
- if you are pregnant or breast-feeding.

Warnings and precautions
Cytisinicline should be used with caution in case of ischemic heart disease, heart failure, hypertension, pheochromocytoma (a tumour of the adrenal gland), atherosclerosis (hardening of the arteries) and other peripheral vascular diseases, gastric and duodenal ulcer, gastroesophageal reflux disease, hyperthyroidism (overactive thyroid), diabetes, schizophrenia, kidney and liver failure.
Cytisinicline should be taken only by those with a serious intention of weaning off nicotine. The use of Cytisinicline and continuation of smoking could lead to aggravated side effects of nicotine.

Children and adolescents
Due to limited experience, the drug is not recommended for use in persons under 18 years of age.

Elderly population
Due to limited clinical experience, Cytisinicline is not recommended for use in elderly patients over 65 years of age.

Patients with kidney and liver impairment
There is no clinical experience of Cytisinicline in patients with kidney or liver impairment, therefore the medicine is not recommended for use in these patients.

Other medicines and Cytisinicline
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Do not take Cytisinicline with anti-tuberculosis drugs.

In some cases as a result of stopping smoking, with or without Cytisinicline an adjustment of the dose of other medicines may be necessary. This is especially important if you use other medicines which contain theophylline (to treat asthma), tacrine (for Alzheimer's disease), clozapine (for schizophrenia) and ropinirole (to treat Parkinson's disease). If you are not sure, talk to your doctor or pharmacist.

It is currently unknown whether Cytisinicline may reduce the effectiveness of systemically acting hormonal contraceptives. If you are using systemically acting hormonal contraceptives, you should add a second barrier method (e.g. condoms).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You must use effective methods of contraception if you are a woman of childbearing potential. Ask your doctor for advice.
Cytisinicline is contraindicated during pregnancy and breastfeeding.

Driving and using machines
Cytisinicline has no influence on the ability to drive and use machines.

Effect of smoking cessation
The effects of changes in your body resulting from stopping smoking, with or without treatment with Cytisinicline, may alter the way other medicines act. Therefore, in some cases an adjustment of the dose may be necessary. See above under 'Other medicines and Cytisinicline for further details.

For some people, stopping smoking with or without treatment has been associated with an increased risk of experiencing changes in thinking or behaviour, feelings of depression and anxiety (rarely including suicidal ideation and suicide attempt) and can be associated with a worsening of psychiatric disorder. If you have a history of psychiatric disorder you should discuss this with your doctor.

3. How to use Cytisinicline

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
One package of Cytisinicline (100 tablets) is sufficient for a complete therapy. The duration of treatment is 25 days. Cytisinicline is for oral use and it should be taken with a suitable amount of water according to the following schedule.

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

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. In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months.

If you use more Cytisinicline than you should
Symptoms of nicotine intoxication are observed in Cytisinicline overdose. Symptoms of overdose include malaise, nausea, vomiting, increased heart rate, fluctuations in blood pressure, breathing problems, blurred vision, convulsions.
If you have only one of described symptoms or the symptom, which is not mentioned in this leaflet, stop taking Cytisinicline and contact your doctor or pharmacist.

If you forget to use Cytisinicline
Do not take a double dose to make up for a forgotten dose.

If you stop using Cytisinicline
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

Very common may affect more than 1 user in 10: change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, increased blood pressure (hypertension), dry mouth, diarrhea, rash, fatigue, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, increased heart rate, nausea, changes flavour, 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, tearing, dyspnea, increased sputum, excessive salivation, sweating, decreased elasticity of the skin, tiredness, increase in serum transaminase levels.

Most of above side effects occur at the beginning of the therapy and resolve along with its duration. These symptoms could also be the result of smoking cessation (withdrawal symptoms), not treatment with Cytisinicline.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cytisinicline

Keep this medicine out of the sight and reach of children.
Store below 25°C in the original package in order to protect from moisture and light.
Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cytisinicline contains

- The active substance is cytisinicline (previously used name: cytisine). One tablet contains 1.5 mg of cytisinicline.
- The other ingredients are: mannitol, cellulose, microcrystalline, magnesium stearate, glycerol dibehenate, hypromellose.

What Cytisinicline looks like and contents of the pack

Cytisinicline is round, biconvex, white tablet with diameter 6 mm.

PVC/PCTFE/Aluminium or PVC/PE/PVDC/Aluminium blisters placed into cardboard box containing 100 tablets.

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