

## **Package leaflet: Information for the user**

### **Cytisinicline APC Pharmlog 1.5 mg film-coated 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**

1. What Cytisinicline APC Pharmlog is and what it is used for
2. What you need to know before you use Cytisinicline APC Pharmlog
3. How to use Cytisinicline APC Pharmlog
4. Possible side effects
5. How to store Cytisinicline APC Pharmlog
6. Contents of the pack and other information

#### **1. What Cytisinicline APC Pharmlog is and what it is used for**

Cytisinicline APC Pharmlog contains the active substance cytisinicline.

This medicine is used for smoking cessation and reduction of nicotine cravings in adult smokers who are willing to stop smoking. The treatment goal of Cytisinicline APC Pharmlog is the permanent cessation of the nicotine-containing products use.

The use of Cytisinicline APC Pharmlog allows for a gradual reduction of nicotine dependence without nicotine withdrawal symptoms (e.g. depressed mood, irritability, anxiety, difficulty concentrating, insomnia, increased appetite).

#### **2. What you need to know before you use Cytisinicline APC Pharmlog**

##### **Do not use Cytisinicline APC Pharmlog:**

- if you are allergic to cytisinicline 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 APC Pharmlog 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,
- impaired kidney and liver function.

Cytisinicline APC Pharmlog should be taken only by those with a serious intention of weaning off nicotine. The use of Cytisinicline APC Pharmlog and continuation of smoking or use of products containing nicotine could lead to aggravated side effects of nicotine.

You must use effective methods of contraception if you are a woman of childbearing potential. See also the point “Pregnancy and breast-feeding”.

### **Children and adolescents**

Due to limited experience, Cytisinicline APC Pharmlog is not recommended for use in persons under 18 years of age.

### **Elderly population**

Due to limited clinical experience, Cytisinicline APC Pharmlog 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 APC Pharmlog in patients with kidney or liver impairment, therefore the medicine is not recommended for use in these patients.

### **Other medicines and Cytisinicline APC Pharmlog**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Cytisinicline APC Pharmlog with anti-tuberculosis drugs.

In some cases as a result of stopping smoking, with or without Cytisinicline APC Pharmlog 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 APC Pharmlog 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.

#### Contraception in women

You must use effective methods of contraception if you are a woman of childbearing potential.

It is currently unknown whether Cytisinicline APC Pharmlog 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).

Ask your doctor for advice.

#### Pregnancy and breast-feeding

Cytisinicline APC Pharmlog must not be used during pregnancy and breastfeeding.

### **Driving and using machines**

Cytisinicline APC Pharmlog has no influence on the ability to drive and use machines.

### **Stopping smoking**

The effects of changes in your body resulting from stopping smoking, with or without treatment with Cytisinicline APC Pharmlog, 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 APC Pharmlog 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.

### **Cytisinicline APC Pharmlog contains aspartame**

This medicine contains 0.12 mg aspartame in each film-coated tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

## **3. How to use Cytisinicline APC Pharmlog**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

One package of Cytisinicline APC Pharmlog (100 tablets) is sufficient for a complete therapy. The duration of treatment is 25 days. Cytisinicline APC Pharmlog is for oral use and it should be taken with a suitable amount of water according to the following schedule.

<b>Days of treatment</b>	<b>Recommended dosing</b>	<b>Maximum daily dose</b>
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

Blister is labelled with the consecutive days of taking Cytisinicline APC Pharmlog.

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.

### **Use in children and adolescents**

Cytisinicline APC Pharmlog is not recommended for use in patients under 18 years of age.

### **If you use more Cytisinicline APC Pharmlog than you should**

Symptoms of nicotine intoxication are observed in Cytisinicline APC Pharmlog 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 APC Pharmlog and contact your doctor.

### **If you forget to use Cytisinicline APC Pharmlog**

Do not take a double dose to make up for a forgotten dose.

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 APC Pharmlog.

### **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 HPRA Pharmacovigilance Website [www.hpra.ie](http://www.hpra.ie).

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

## **5. How to store Cytisinicline APC Pharmlog**

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. 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 APC Pharmlog contains**

- The active substance is cytisinicline (the previously used name: cytisine). Each film-coated tablet contains 1.5 mg of cytisinicline.
- The other ingredients are:

Tablet core:

Hypromellose

Mannitol

Maize starch

Magnesium aluminometasilicate

Silica colloidal anhydrous

Magnesium stearate.

Film-coat:

Hypromellose (E464)

Microcrystalline cellulose (E460)

Talc (E553b)

Glycerol (E422)

Titanium dioxide (E171)

Quinoline yellow Aluminium-lake (E104)

Indigo carmine (blue 2) Aluminium-lake (E132)

Menthol flavour powder

Aspartame (E 951).

See section 2 “Cytisinicline APC Pharmlog contains aspartame”.

### **What Cytisinicline APC Pharmlog looks like and contents of the pack**

Cytisinicline APC Pharmlog are round, biconvex film-coated tablets, light green to greenish, with diameter 5 mm.

Cytisinicline APC Pharmlog is available in blisters containing 100 film-coated tablets.

**Marketing Authorisation Holder**

Adamed Pharma S.A.  
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05-152 Czosnów  
Poland

**Manufacturer**

Adamed Pharma S.A.  
ul. Marszałka J. Piłsudskiego 5  
95-200 Pabianice  
**Poland**

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Germany: Cytisiniclin APC Pharmlog  
Poland, Sweden: Cytisinicline APC Pharmlog  
Italy: Cytisiniclina APC Pharmlog  
Ireland: Cytisinicline APC Pharmlog 1.5 mg film-coated tablets  
Spain: Cytisinicline APC Pharmlog comprimidos recubiertos con película, 1,5 mg

**This leaflet was last revised in**