

## Package leaflet: Information for the user

### Minreksav 1.5 mg/pump actuation oral solution

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

#### **1. What Minreksav is and what it is used for**

Minreksav contains the active substance cytisinicline, also known as cytisine.

This medicine is used in nicotine dependence.

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 using Minreksav is the permanent cessation of the nicotine-containing products use.

The use of Minreksav allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms (e.g. depressed mood, irritability, anxiety, difficulty concentrating, insomnia, increased appetite).

#### **2. What you need to know before you use Minreksav**

##### **Do not use Minreksav:**

- 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**

Talk to your doctor or pharmacist before using Minreksav 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.

Minreksav should be taken only by those with a serious intention of weaning off nicotine. The use of Minreksav and continuation of smoking could lead to aggravated side effects of nicotine.

### **Children and adolescents**

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

### **Elderly population**

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

### **Other medicines and Minreksav**

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

Do not take Minreksav with anti-tuberculosis drugs.

In some cases as a result of stopping smoking with or without Minreksav 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 Minreksav 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 Minreksav 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

Minreksav is must not be used during pregnancy and breastfeeding.

### **Driving and using machines**

Minreksav has no or negligible influence on ability to drive and use machines.

### Stopping smoking

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

### Minreksav contains ethanol, propylene glycol, sodium and sodium metabisulfite

This medicine contains 0.17 mg of alcohol (ethanol) in each dose (0.19 ml) which is equivalent to 90.00 mg/100 ml (0.09% w/v). The amount in single dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 44.87 mg propylene glycol in each dosage (0.19 ml) which is equivalent to 237.53 mg/ml.

This medicine contains less than 1 mmol sodium (23 mg) per dosage, that is to say essentially ‘sodium-free’.

This medicine contains sodium metabisulfite. May rarely cause severe hypersensitivity reactions and bronchospasm.

### 3. How to use Minreksav

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

One package of Minreksav (100 pump actuations) is sufficient for a complete therapy. The duration of treatment is 25 days.

Recommended dose

Minreksav should be taken according to the following schedule:

Days of treatment	Recommended dosing	Maximum daily dose
From the 1st to the 3rd day	1 pump actuation every 2 hours	6 pump actuations
From the 4th to the 12th day	1 pump actuation every 2.5 hours	5 pump actuations
From the 13th to the 16th day	1 pump actuation every 3 hours	4 pump actuations
From the 17th to the 20th day	1 pump actuation every 5 hours	3 pump actuations
From the 21st to the 25th day	1-2 pump actuations a day	to 2 pump actuations

Smoking should be stopped no later than on the 5th day of treatment. The person who stopped smoking or use of products containing nicotine must not smoke even a single cigarette. This is essential to achieve a therapeutic success. In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months.

### Use in children and adolescents

Minreksav is not recommended for use in persons under 18 years of age.

### **Use in elderly population**

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

### **Use in patients with kidney and liver impairment**

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

### Method of administration

Minreksav is for oral use and may be taken with or without water/liquid.

### Pump unlocking and usage recommendations

- Remove the protective cap of the applicator.
- Position the container in a way that the pump is on top of the container.
- The pump must be primed through pressing the top of the container (pump) with index finger 5 times, until a fine dose appears. After initial priming (which is necessary only when using the product for the first time) each actuation delivers 1.5 mg cytisinicline.
- Right after priming, the nozzle will be pointed as close to the open subject's mouth as possible.
- Press the top of the dispenser once and release one dose into the mouth, avoiding the lips and contact with parts of the oral cavity.
- After usage, place the protective cup back on the applicator.

### **If you use more Minreksav than you should**

Symptoms of nicotine intoxication are observed in Minreksav 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 Minreksav and contact your doctor or pharmacist.

### **If you forget to use Minreksav**

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

### **If you stop using Minreksav**

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.

### **Very common may affect more than 1 in 10 people:**

- change in appetite (mainly increase),
- weight gain,
- headaches,
- irritability,
- sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares),
- mood changes,
- anxiety,
- increased heart rate,
- increased blood pressure (hypertension),
- dry mouth,

- abdominal pain (especially in the upper abdomen),
- nausea,
- rash,
- muscle pain.

**Common may affect up to 1 in 10 people:**

- dizziness,
- difficulty in concentration,
- slow heart rate,
- vomiting,
- changes flavour,
- constipation,
- diarrhea,
- abdominal distension,
- burning tongue,
- heartburn,
- fatigue,
- malaise.

**Uncommon affects up to 1 in 100 people:**

- 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 (liver enzymes).

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 Minreksav.

**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: HPRC 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 Minreksav**

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

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. Do not refrigerate or freeze.

Shelf life after the first opening: 6 months.

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 Minreksav contains**

- The active substance is cytisinicline (the previously used name: cytisine). One dose (pump actuation) contains 1.5 mg of cytisinicline.
- The other ingredients are: xylitol (E 967), sodium dihydrogen phosphate dihydrate, glycerol, propylene glycol, sodium metabisulfite (E 223), liquid mint aroma (that contains: ethanol, anhydrous, propylene glycol (E1520), purified water, flavouring preparations, natural flavouring substances), purified water.

### **What Minreksav looks like and contents of the pack**

Minreksav is colourless to yellow, clear, solution.

White HDPE multidose container with metering pump with the cap. Content of solution in a multidose container is 22.0 ml, which corresponds to at least 100 doses. The container is placed in the carton box.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Profit Sylwia Gil  
ul. Wołodyjowskiego nr 19  
05-502 Piaseczno  
Poland

### **Manufacturer**

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

Curtis Health Caps S.A.  
Wysogotowo, Batorowska 52  
62-081 Przeźmierowo  
Poland

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

Poland: Isamuxal  
Ireland: Minreksav 1.5 mg/pump actuation, oral solution

**This leaflet was last revised in**