

DESMOXAN

1.5mg Cytisinum Capsule

Consumer Medicine Information

Please read this information before you start using this medicine.

Always take this medicine exactly as described in this leaflet or as indicated by your doctor or pharmacist.

- Keep this leaflet with the medicine. You may need to read it again.
- If you have any concerns about taking Desmoxan or require further information or advice, ask your doctor or pharmacist.
- If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 weeks.

What is in this leaflet?

1. What Desmoxan is and what it is used for?
2. Important information before you take Desmoxan
3. How to use Desmoxan?
4. Possible side effects
5. How to store Desmoxan?
6. Contents of the pack and other information

1. What is Desmoxan and what it is used for?

Desmoxan is a drug which contains an active substance—cytisine, and its effect is similar to that of nicotine. Cytisine gradually displaces nicotine from the body. Therefore, the nicotine addiction is reduced, and it is possible to break the habit of smoking tobacco without the withdrawal effects (nicotine craving).

Therapeutic indications

The drug is used in the treatment of nicotine addiction. Using Desmoxan enables gradual reduction of addiction to nicotine, and breaking the habit of tobacco smoking, without the nicotine withdrawal effects.

The final purpose of taking Desmoxan is to permanently cease using products with nicotine.

2. Important information before you take Desmoxan

When not to take Desmoxan?

- if you are hypersensitive or allergic to the active substance (cytisine) or any of the product's excipients (listed in section 6);
- if you have uncontrolled hypertension (systolic blood pressure >179 mmHg or diastolic blood pressure >109 mmHg);
- if you have unstable angina;
- if recently you have had a heart attack or stroke;
- if you have clinically significant heart rhythm disorders;
- if you have pheochromocytoma;
- if you have hyperthyroidism;
- if you are pregnant or breastfeeding.

Warnings and precautions

Desmoxan should be used only by patients with firm intention to give up smoking tobacco.

Using Desmoxan while smoking tobacco may worsen the adverse effects of nicotine.

Talk to your doctor or pharmacist before taking Desmoxan if you:

- have ischaemic heart disease, heart failure, cerebrovascular disease, obliterative arterial diseases, arterial hypertension, gastroduodenal ulcerative disease,

gastroesophageal reflux disease, hyperthyroidism, diabetes (should be used in caution with those who are on insulin treatment), schizophrenia, epilepsy, renal and hepatic impairment; or

- are an elderly patient (over 65 years old).

In such cases, the risk-benefit balance should be carefully assessed before taking the product as there is not sufficient clinical experience with Desmoxan administration for these categories of patients.

Other medicines and Desmoxan

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

The analeptic effect of cytisine decreases during combined therapy with anti-tuberculosis drugs (PASA and streptomycin).

No clinical data pertaining to interaction with other drugs.

Pregnancy and breast-feeding

Do not use this medicine while you are pregnant or breastfeeding.

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Desmoxan has no effect on ability to drive and use machines.

3. How to use Desmoxan?

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

One package of this medicinal product is sufficient for a complete treatment. The treatment duration is 25 days and the following regimen should be followed:

Recommended dosage

From day 1 to day 3	1 capsule every 2 hours (maximum of 6 capsules a day)
from day 4 to day 12	1 capsule every 2.5 hours (maximum of 5 capsules a day)
from day 13 to day 16	1 capsule every 3 hours (maximum of 4 capsules a day)
from day 17 to day 20	every 5 hours (maximum of 3 capsules a day)
from day 21 to day 25	1-2 capsules a day

Take Desmoxan orally with some water.

From the very first day of treatment, you should gradually decrease the number of smoked cigarettes.

A person smoking tobacco should give up smoking completely not later than on day 5 of the treatment. A person who quit smoking cannot under any circumstances smoke even one cigarette. Duration of the effect of the treatment depends on it.

If the effect is not satisfactory, you should stop the treatment. The treatment can be started again after 2 – 3 months.

Paediatric population

Do not use the product in children under 18 years of age without consultation with a doctor.

The safety and effectiveness of the medicinal product has not been determined yet.

If you take more Desmoxan than you should

If you take more Desmoxan than you should, contact your doctor immediately.

Overdose symptoms may occur, such as:

- nausea, vomiting,
- increased heart rate,
- higher arterial blood pressure,
- breathing problems,
- constricted pupils,
- lower arterial pressure,
- slow heart rate,
- dyspnoea,
- respiratory failure,
- coma.

In all cases of overdose, symptomatic treatment must be applied: gastric lavage (if possible), glucose and physiological saline infusions, anticonvulsive drugs, cardio-tonic drugs, drugs stimulating the respiratory system. Blood pressure, breathing and heart rate should be monitored.

If you forget to take Desmoxan

Take the drug as soon as possible, and take the next dose as usual.

Do not take a double dose to make up for the missed one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Desmoxan can have side effects, although not everybody experiences them.

The side effects usually occur at the beginning of the treatment. They include:

- fatigue, malaise, tiredness,
- lacrimation,
- changes in appetite (mostly increased appetite), increased body weight,
- headaches, dizziness, irritation, heaviness of the head,
- sleep disorders (sleeplessness, drowsiness, strange dreams, nightmares, somnolence),
- mood swings, anxiety, problems with concentration,
- decreased libido,
- increased or decreased heart rate,
- increased arterial blood pressure,
- dyspnoea, increased coughing up,
- dryness in the mouth, excessive salivation,
- gastrointestinal disorders (stomachache, nausea, vomiting, constipation, diarrhoea, flatulence, heartburn),
- burning of the tongue, changes in taste,
- muscle pains,
- rash, increased sweating, reduced skin elasticity,
- increased activity of aminotransferases (certain type of hepatic enzymes).

Most side effects disappear during the treatment.

If you notice any of the side effects listed above, please stop using the drug and contact your doctor.

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 to the UNSW research team:

University of New South Wales

National Drug and Alcohol Research Centre

Sydney, NSW 2052

Phone: 1800 214 640

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

5. How to store Desmoxan?

Keep out of the reach and sight of children.

Store in the original packaging at a temperature below 25°C.

Do not use the drug after the expiry date which is stated on the blister and package. The expiry date refers to the last day of that month.

Do not discard any medicines to the wastewater system or with household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Desmoxan contains?

- The active substance is cytisine.
- One hard capsule contains 1.5 mg of cytisine (*Cytisimum*).
- Other ingredients: microcrystalline cellulose; maize starch; colloidal silica, anhydrous; magnesium stearate.

Composition of the hard capsule: titanium dioxide, indigotin, gelatin.

What Desmoxan looks like and contents of the package?

Desmoxan is in the form of hard gelatin capsules, white and blue, filled with light yellow powder. The package contains 100 hard capsules. The blisters and a leaflet are packed in a cardboard box.

Marketing Authorisation Holder and Manufacturer

Aflofarm Farmacja Polska Sp. z o. o.

ul. Partyzancka 133/151

95-200 Pabianice

tel: 0011+48(42) 22 53 100