

Package leaflet: information for the user

Decigatan, 1.5 mg, tablets  
Cytisinicline

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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

Quitting smoking and reducing the need for nicotine for smokers who want to quit smoking. The aim of treatment with Decigatan is for you to permanently stop using nicotine products.

Using Decigatan gradually reduces nicotine dependence by alleviating withdrawal symptoms.

2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine (cytisinicline, previously used name: cytisine). You can find these substances in section 6,
- if you suffer from unstable angina pectoris (unexpected tightness, pressure, painful feeling in the chest),
- if you have recently had a heart attack,
- if you suffer from severe arrhythmias (abnormal heart rhythm),
- if you have recently had a stroke,
- if you are pregnant or breastfeeding.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine if you suffer from ischemic heart disease (lack of blood due to a narrowed or blocked blood vessel), heart failure (insufficient pumping power of the heart), hypertension (high blood pressure), pheochromocytoma (a tumor in the adrenal medulla), atherosclerosis (arterial calcification) and other peripheral vascular diseases (in the arms and/or legs), stomach and intestinal ulcers, gastroesophageal reflux disease, hyperthyroidism (overactive thyroid), diabetes, schizophrenia, kidney and liver failure.

This medicine should only be used by individuals who seriously want to quit using nicotine. Taking this medicine while continuing to smoke may lead to more severe side effects of nicotine.

#### Children and adolescents up to 18 years

Because there is little experience with the use of this medicine by individuals under 18 years, its use is not recommended.

#### Elderly

Because there is little experience with the use of this medicine by individuals over 65 years, its use is not recommended.

#### Patients with impaired liver and/or kidney function

There is no experience with the use of this medicine in patients with impaired liver or kidney function, and therefore its use is not recommended for these patients.

#### Are you taking any other medicines?

Are you using any other medications besides Decigatan, have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist.

Do not use this medication in combination with tuberculostatics (medications used in the treatment of tuberculosis).

If you stop smoking, with or without the use of Decigatan, it may be necessary in certain cases to adjust the dosage of other medications. This is especially important if you are using medications that contain one of the following substances: theophylline (for the treatment of asthma), tacrine (for the treatment of Alzheimer's disease), clozapine (for the treatment of schizophrenia), and ropinirole (for the treatment of Parkinson's disease). If in doubt, contact your doctor or pharmacist.

It is currently unclear whether this medication reduces the effectiveness of hormonal contraceptives (pill, vaginal ring, patch, 'injection pill', and implant rod). If you use hormonal contraception, you should also use a barrier contraceptive (e.g., condoms).

#### Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before taking this medication.

Women of childbearing age should use effective contraceptive methods. Ask your doctor for advice.

You should not use Decigatan if you are pregnant or breastfeeding.

#### Driving and using machines

This medication does not affect the ability to drive and operate machines.

#### Effect of quitting smoking

Quitting smoking, with or without the use of this medication, can cause changes in your body that affect the action of other medications. A dose adjustment (adjustment of the amount of medication you use) may therefore be necessary. See 'Are you using any other medications?' for more information.

Quitting smoking, with or without treatment, may increase the risk in some individuals of changes in thinking and behavior, feelings of depression and anxiety (in rare cases thoughts of suicide and suicide attempts), and may be associated with worsening of psychiatric disorders. If you have a history of psychiatric illness, you should discuss this with your doctor or pharmacist.

### 3. How do you take this medication?

Always take this medication exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

One package of Decigatan (100 tablets) is sufficient for a complete treatment. The duration of the treatment is 25 days. This medication is for oral (by mouth) use and should be taken with sufficient water according to the schedule below.

Days of treatment	Recommended dosage	Maximum daily dose
From day 1 to day 3	Every 2 hours 1 tablet	6 tablets
From day 4 to day 12	Every 2.5 hours 1 tablet	5 tablets
From day 13 to day 16	Every 3 hours 1 tablet	4 tablets
From day 17 to day 20	Every 5 hours 1 tablet	3 tablets
From day 21 to day 25	1-2 tablets per day	No more than 2 tablets

You must completely stop smoking by day 5 of the treatment. Smoking should not be continued during the treatment, as this may worsen side effects. If the treatment fails, it should be discontinued and possibly resumed after 2 to 3 months.

#### Have you taken too much of this medicine?

In case of an overdose of this medicine, symptoms of nicotine poisoning have been observed. Symptoms of an overdose include: general malaise, feeling sick, nausea, vomiting, increased heart rate, blood pressure fluctuations, breathing problems, blurred vision, seizures. Stop using this medicine and contact your doctor or pharmacist if you experience any of the described symptoms or a symptom not described in this leaflet.

#### Have you forgotten to take this medicine?

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

#### If you stop taking this medicine

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

### 4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

Very common (occurs in more than 1 in 10 people):

change in appetite (usually an increase), weight gain, dizziness, irritability, mood swings, anxiety, increased blood pressure (hypertension), dry mouth, diarrhea, rash, fatigue, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headache, increased heart rate, nausea, changes in taste, heartburn, constipation, vomiting, abdominal pain (especially upper abdomen), muscle pain.

Common (occurs in less than 1 in 10 people):

concentration problems, low heart rate, bloated abdomen, burning tongue, general unwell feeling, feeling sick (malaise).

Sometimes (occurs in less than 1 in 100 people):

heavy feeling in the head, decreased libido (sexual desire), watery eyes, shortness of breath, increased mucus production, excessive salivation, sweating, reduced skin elasticity, fatigue, change in blood laboratory values (increased level of serum transaminases).

Most of the above side effects occur at the beginning of the treatment and disappear during the course of the treatment. The symptoms may also be due to quitting smoking itself (withdrawal symptoms) and are not necessarily the result of treatment with this medicine.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Store below 25°C. Keep in the original packaging to protect from moisture and light. Do not use this medicine after the expiry date. You can find this on the box after the abbreviation "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is cytisinicline (previously used name: cytisine). One tablet contains 1.5 mg cytisinicline.
- The other substances in this medicine are: mannitol, cellulose (microcrystalline), magnesium stearate, glyceryl dibehenate, hypromellose.

What does Decigatan look like and what is in a package?

Decigatan is a round, convex, white tablet with a diameter of 6 mm.

The cardboard packaging contains 100 tablets in blister packs of PVC/PCTFE/aluminum or PVC/PE/PVDC/aluminum.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aflofarm Farmacja Polska Sp. z o.o.

Partyzancka 133/151

95-200 Pabianice

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Manufacturer:

Aflofarm Farmacja Polska Sp. z o.o.

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Registered under: RVG 118544

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Denmark, Netherlands, Finland: Decigatan

Bulgaria, Greece: Liberizin

Germany, Austria, Sweden: Asmoken

Hungary: Liberisan

Ireland: Citidaron

Italy: Defucitan

Poland: Desmoxan

Portugal: Dextazin

Romania, Slovakia, Czech Republic: Defumoxan

Spain: Todacitan

United Kingdom (Northern Ireland): Cytisinicline

Norway, France: Liberostin

This leaflet was last approved in: October 2025