

Package leaflet: Information for the user

Septanazal 1 mg/50 mg/ml nasal spray, solution Xylometazoline hydrochloride/Dexpanthenol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

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1. What Septanazal 1 mg/50 mg/ml is and what it is used for

Septanazal 1 mg/50 mg/ml nasal spray contains active substances xylometazoline hydrochloride and dexpanthenol.

Xylometazoline hydrochloride rapidly constricts blood vessels in the nasal mucous membrane and reduces the swelling of the nasal mucous membrane and mucus secretion. In this way the feeling of a blocked nose is reduced. Dexpanthenol is a derivative of the vitamin pantothenic acid, which promotes healing and protects the nasal mucous membrane.

Septanazal 1 mg/50 mg/ml is used:

- for reducing the swelling of the nasal mucous membrane in rhinitis and to promote healing of mucous membrane lesions,
- for relief in non-allergic nasal mucous membrane inflammation (vasomotor rhinitis),
- for the treatment of worsened breathing through the nose after nasal surgery.

This medicine is intended for use in adults and schoolchildren aged 6 years or over.

2. What you need to know before you use Septanazal 1 mg/50 mg/ml

Do not use Septanazal 1 mg/50 mg/ml:

- if you or your child are allergic to xylometazoline hydrochloride, dexpanthenol or any of the other ingredients of this medicine (listed in section 6),
- if you or your child have a dry inflammation of the nasal mucous membrane with formation of crusts (rhinitis sicca),
- if you or your child have had a surgical removal of the pituitary gland or other surgery exposing the meninges (lining of the brain).

This medicine should not be used in children under 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Septanazal 1 mg/50 mg/ml:

- if you or your child are taking monoamine oxidase inhibitors (MAOIs) or other medicines that

- can raise blood pressure,
- if you or your child have elevated pressure inside the eye (glaucoma), particularly if you suffer from narrow-angle glaucoma,
- if you or your child have severe cardiovascular disease (e.g. coronary heart disease, high blood pressure, prolonged QT syndrome),
- if you or your child have adrenal marrow tumour (pheochromocytoma),
- if you or your child have a metabolic disease (e.g increased activity of the thyroid gland presenting with increased sweating, increased body temperature, increased heart rate or if you have diabetes),
- if you or your child have a metabolic disorder called porphyria,
- if you or your child have an enlarged prostate.

Use during chronic rhinitis may only be carried out under medical supervision owing to the danger of the atrophy of the nasal mucosa.

Incorrect use or use of the excessive amounts of the spray can cause systemic undesirable effects, particularly in children (see section 4).

The use of this drug at long intervals or higher doses may cause chronic swelling of the nasal mucosa and possibly thinning (damage).

It is not recommended that you or your child use this product if you or your child are already using:

- any other medicines for the treatment of the flu,
- any other cough-and-cold medicines containing sympathomimetics (medicines used to treat nasal congestion such as pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline, tuaminoheptane).

Concomitant use of these medicines with Septanazal 1 mg/50 mg/ml may increase the risk of undesirable effects on the cardiovascular system and central nervous system.

Avoid direct contact of this medicine with the eyes.

Children

Do not use doses higher than those recommended by the doctor. Please consult your doctor regarding duration of treatment and frequency of use in children.

Septanazal 1 mg/50 mg/ml is suitable for use only in children over 6 years of age. For children under 6 years of age, Septanazal for children nasal spray with lower doses of active substances is available.

You should supervise the use of this medicine in children under 12 years of age.

If the child does not feel better or feels worse after 3 days of treatment, please consult the doctor.

Other medicines and Septanazal 1 mg/50 mg/ml

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

Concomitant use of Septanazal 1 mg/50 mg/ml with medicinal products that lower blood pressure (eg methyldopa) should be avoided due to the potential blood pressure-increasing effect of xylometazoline.

Using Septanazal 1 mg/50 mg/ml at the same time as some medicines for the treatment of depression (monoamine oxidase inhibitors) as well as medicines which increase blood pressure may lead to an increase in blood pressure.

Using Septanazal 1 mg/50 mg/ml at the same time as some other flu medicines or cough-and-cold medicines containing sympathomimetics (medicines used to treat nasal congestion such as pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline,

naphazoline, tuaminoheptane) may increase the undesirable effects on the cardiovascular and central nervous system.

Consult a doctor before using Septanazal 1 mg/50 mg/ml if you or your child use any of the above-mentioned medicines.

Septanazal 1 mg/50 mg/ml with food and drink

You can use this medicine irrespective of meals.

Pregnancy and breast-feeding and fertility

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.

This medicine should not be used during pregnancy due to a lack of safety data in pregnant women.

This medicine should not be used during breast-feeding, since it is not known whether xylometazoline hydrochloride passes into breast milk.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines when used as recommended.

Septanazal 1 mg/50 mg/ml contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per injection, ie is essentially 'sodium-free'.

3. How to use Septanazal 1 mg/50 mg/ml

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

The recommended dose for adults is one spray into each nostril up to 3 times a day as needed. The dosage depends on individual sensitivity and clinical efficacy.

Duration of treatment

In general, treatment should not last longer than 7 days. You should wait a few days before you can reuse this medicine.

Always consult your doctor about the duration of treatment in children.

Method of administration

First remove the protective cap from the sprayer.

Before the first use or if the spray has not been used for a long period of time, press the spray head several times until a fine spray appears.



Insert the sprayer tip as upright as possible into one nostril and press the spray head once. Gently

inhale through the nose while spraying. If necessary, repeat the procedure for the other nostril. After each use, wipe the sprayer tip with a paper tissue and place the protective cap back on the sprayer.



Patients with elevated pressure inside the eye (glaucoma), especially narrow-angle glaucoma, should consult a doctor before using this medicine.

If you use more Septanazal 1 mg/50 mg/ml than you should

If you use more of this medicine than you should or if you accidentally ingest large quantities of the medicine, the following side effects might occur: constriction of the eye pupils (miosis), expansion of the eye pupils (mydriasis), fever, sweating, paleness of the skin, blue coloration of the lips (cyanosis), nausea, convulsions, cardiac and vascular disorders (increased heart rate, slow heart rate, heart rhythm disorders, circulatory failure, cardiac arrest, high blood pressure (hypertension)), respiratory disorders (swelling of the lungs, breathing problems), and mental disorders.

You may also experience drowsiness, decreased body temperature, heart rate decelerations, and decrease in blood pressure, respiratory arrest and coma.

If you notice any of these symptoms, contact your doctor immediately.

If you forget to use Septanazal 1 mg/50 mg/ml

Do not use 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.

Uncommon (may affect up to 1 in 100 people):

- hypersensitivity reaction such as swelling of the skin and mucous membranes, skin rash, itching.

Rare (may affect up to 1 in 1,000 people):

- palpitations (feeling your heartbeat), tachycardia (faster heartbeat), hypertension (high blood pressure).

Very rare (may affect up to 1 in 10,000 people):

- restlessness, hallucinations (primarily in children),
- difficulty in sleeping, fatigue (drowsiness, sedation), headache,
- heart rhythm disorders (arrhythmias),
- swelling of the nasal mucous membrane (after discontinuation of the treatment), nosebleed,
- seizures (convulsions; especially in children).

Not known (frequency cannot be estimated from the available data):

- burning and dryness of the nasal mucous membrane, sneezing.

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 listed in www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Septanazal 1 mg/50 mg/ml

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening of the container, the product should be used within 12 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 Septanazal 1 mg/50 mg/ml contains

- The active substances are xylometazoline hydrochloride and dexpanthenol.
One ml of nasal spray, solution, contains 1 mg xylometazoline hydrochloride and 50 mg dexpanthenol.
One spray contains 0.1 ml of nasal spray, solution, containing 0.1 mg xylometazoline hydrochloride and 5.0 mg dexpanthenol.
- The other ingredients are potassium dihydrogen phosphate, disodium phosphate dodecahydrate and water, purified. See section 2 “Septanazal 1 mg/50 mg/ml contains sodium”.

What Septanazal 1 mg/50 mg/ml looks like and contents of the pack

Nasal spray, solution (nasal spray) is clear, colourless liquid solution.

Septanazal 1 mg/50 mg/ml is available in boxes of 10 ml of nasal spray, solution, in a plastic spray container with spray pump. 10 ml of nasal spray, solution is sufficient for 100 sprays.

Marketing Authorisation Holder

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

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