

Package leaflet: Information for the user

Septanazal for children 0.5 mg/50 mg in 1 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 your child do not feel better or if your child feels worse after 3 days.

What is in this leaflet

1. What Septanazal for children is and what it is used for
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1. What Septanazal for children is and what it is used for

Septanazal for children nasal spray contains 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 for children is used:

- for reducing the swelling of the nasal mucous membrane in nasal mucous membrane inflammation (rhinitis) and to promote healing of mucous membrane lesions,
 - for relief in non-allergic nasal mucous membrane inflammation (vasomotor rhinitis).
- Upon medical advice only, Septanazal for children is also used for the treatment of worsened breathing through the nose after nasal surgery.

This medicine is intended for use in children aged 2 to 6 years.

2. What you need to know before you use Septanazal for children

Do not use Septanazal for children

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

This medicine must not be used in children under 2 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Septanazal for children:

- if your child is taking monoamine oxidase inhibitors (MAOIs) or other medicines that can raise blood pressure,
- if your child has elevated pressure inside the eye (glaucoma), particularly, if your child suffers from narrow-angle glaucoma,
- if your child has severe cardiovascular disease (e.g. coronary heart disease, high blood pressure, long QT syndrome),
- if your child has adrenal marrow tumour (pheochromocytoma),
- if your child has a metabolic disease (e.g increased activity of the thyroid gland presenting with increased sweating, increased body temperature, increased heart rate or if your child has diabetes),
- if your child has a metabolic disorder called porphyria,
- if your child has an enlarged prostate.

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

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

It is not recommended that you give this product to your child if he/she is already receiving:

- 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 for children 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

Septanazal for children is suitable for use only in children aged 2 to 6 years. For children over 6 years of age, Septanazal for adults nasal spray with higher strength of the active substance xylometazoline hydrochloride is available.

You should supervise the use of this medicine in your child.

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

Other medicines and Septanazal for children

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

Using Septanazal for children at the same time as some medicines for the treatment of depression (monoamine oxidase inhibitors of the tranylcypromine type or tricyclic antidepressants) as well as medicines which increase blood pressure may lead to an increase in blood pressure due to the cardiovascular effects of these substances.

Using Septanazal for children 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 system and central nervous system.

Consult a doctor before using Septanazal for children if your child is receiving any of the above-mentioned medicines.

Pregnancy, 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.

3. How to use Septanazal for children

Always use 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.

The recommended dose for children aged 2 to 6 years is one actuation into each nostril up to 3 times a day as needed. The dosage depends on individual sensitivity and clinical efficacy. You must talk to a doctor if symptoms persists after 3 days.

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 5 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.



Prolonged use or use of higher doses of this medicine may result in chronic swelling and possibly thinning (damage) of the nasal mucous membrane.

If you use more Septanazal for children 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 for children

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 skin rash, itching, swelling of the skin and mucous membranes.

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, difficulty in sleeping, fatigue (drowsiness, sedation), headache, hallucinations (primarily in children),
- 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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Septanazal for children

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 for children contains

- The active substances are xylometazoline hydrochloride and dexpanthenol.
Each ml of nasal spray, solution, contains 0.5 mg xylometazoline hydrochloride and 50 mg dexpanthenol.
One actuation contains 0.1 ml of nasal spray, solution, containing 0.05 mg xylometazoline hydrochloride and 5.0 mg dexpanthenol.
- The other ingredients are potassium dihydrogen phosphate, disodium phosphate dodecahydrate and water for injections.

What Septanazal for children looks like and contents of the pack

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

Septanazal for children 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 90 actuations.

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

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Xylometazolin/dexpanthenol Krka
Germany	Septanasal für Kinder
Portugal	Septanazal para crianças
Ireland	Septanazal for children

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