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. The nasal mucous membrane and mucus secretion, if this may be the feeling of a stuffy nose.

Septanazal for children is used:

- to reduce the swelling of the nasal mucous membrane in nasal congestion;
- to prevent swelling of mucous membranes (vasomotor rhinitis);
- to reduce the sensitivity of mucous membrane lesions;
- for local anesthesia in 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

If you have any questions about this medicine, ask your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 before using this medicine for the first time.

4. Possible side effects

If you have any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. Contents of this leaflet

‘Package leaflet: Information for the patient’ contains any possible side effects not listed in this leaflet. Ask your pharmacist if you need more information or advice.

Keep this leaflet. You may need to read it again.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always read the leaflet before you start using any medicine. It is caused by nasal congestion.

6. Contents of the pack and other information

Contains any possible side effects not listed in this leaflet. Ask your pharmacist if you need more information or advice.

Keep this leaflet. You may need to read it again.
Septanazal for children
Xylometazolin/ Dexpanthenol Krka

Septanazal infantil

The active substances are xylometazoline hydrochloride and dexpanthenol.
What Septanazal for children contains
Nasal spray, solution, contains 0.1 mg xylometazoline hydrochloride and 5 mg dexpanthenol.

What Septanazal for children looks like and contents of the pack
Septanazal for children is available in boxes of 10 ml of nasal spray, solution, in a plastic spray container with spray pump. On-the-go spray solution is sufficient for 9 sprays.

Marketing Authorisation Holder
IRL - KRKA, d.d., Novo mesto, Slovenia; EMEA ref.: 1087 MV

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

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

Slovenia
KRKA, d.d., Novo mesto, Slovenia; EMEA ref.: 1087 MV

This leaflet was last revised in

6. Contents of the pack and other information

• norepinephrine concentration, thinning (damage) of the nasal mucous membrane.

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

• hypereosinophilic reaction such as skin rash, itching, swelling of the skin, and mucous membranes.

• irritable or expulsive diarrhea.

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

• hypotension (low blood pressure), fever, sweating, paleness of the skin.

• expansion of the eye pupils (mydriasis), fever, sweating, paleness of the skin.

• side effects might occur: constriction of the eye pupils (miosis), fever, sweating, paleness of the skin.

• nausea, convulsions, especially in children.

• seizures (convulsions; especially in children).

• restlessness, difficulty in sleeping, fatigue (drowsiness, sedation), palpitations (feeling your heartbeat), tachycardia (faster heartbeat), heart rhythm disorders, circulatory failure, cardiac arrest, high blood pressure (hypertension), respiratory disorders (swelling of the lungs, breathing problems), and mental disorders.

• skin and mucous membranes.

• changes in body temperature, blue coloration of the lips (cyanosis), nausea, convulsions, especially in children.

• palpitations (feeling your heartbeat), tachycardia (faster heartbeat), heart rhythm disorders, circulatory failure, cardiac arrest, high blood pressure (hypertension), respiratory disorders (swelling of the lungs, breathing problems), and mental disorders.

• headache, photophobia, sleep disturbance (insomnia in children).

• vision disorders (amblyopia).

• norepinephrine concentration, thinning (damage) of the nasal mucous membrane.

• nausea (nausea, vomiting, worsened nausea, retching), swelling of the skin, and mucous membranes.

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• seizures (convulsions; especially in children).

• restlessness, difficulty in sleeping, fatigue (drowsiness, sedation), headache, hallucinations (especially in children).

• psychosis (psychosis), anxiety, agitation, excitement in children.

• hyperthyroid disorders (hyperthyroidism).

• narrow-angle glaucoma, should consult a doctor before using this medicine.

Patients with elevated pressure inside the eye (glaucoma), especially those with obstructive sleep apnoea, should consult a doctor before using this medicine.

The recommended dose for children aged 2 to 6 years is one spray into each nostril up to 3 times a day as needed. Regarding the duration of use in children, you should always consult a doctor.

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Prolonged use or use of higher doses of this medicine may result in drug tolerance and drug dependence.

You may also experience dryness of the nasal mucous membrane, sneezing.

Chronic swelling and possibly thinning (damage) of the nasal mucous membrane.

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Do not use Septanazal for children in children with narrow-angle glaucoma.

If you use more of this medicine than you should or if you accidentally ingest large quantities of the medicine, the following side effects may occur: vomiting, worsened nausea, retching, changes in body temperature, blue coloration of the lips (cyanosis), nausea, convulsions, especially in children.

If you use more Septanazal for children than you should

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.

If you forget to use Septanazal for children

If you stop using Septanazal for children

If you use more Septanazal for children than you should

first secure the protective cap from the spray. 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 spray tip as upright as possible into one nostril and push the spray head into the nostril. Gently inhale through the nose while pressing the spray head once. Gently inhale through the nose while pressing the spray head once. Gently inhale through the nose while pressing the spray head once. Gently inhale through the nose while pressing the spray head once.

If you do not need it, you can stop using Septanazal for children as soon as you no longer need it.

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

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Possible side effects

Use all medicines, this medicine can cause side effects, although not everybody gets them.

The duration of use in children, you should always consult a doctor.

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

If you stop using Septanazal for children as soon as you no longer need it.

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If you forget to use Septanazal for children

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

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