Rhinxyl HA

0.5 mg/ml nasal spray, solution
Xylometazoline hydrochloride

Leaflet: Information for users

Please read this leaflet carefully and completely before you start using this medicine as it contains important information for your child.
Always use this medicine as directed on this leaflet or as directed by your doctor or pharmacist.
- Keep this leaflet. You may need to re-read it.
- Ask your pharmacist if you need more information or recommendations.
- If your child experiences any side effects, contact your doctor or pharmacist. These include any possible side effects not mentioned on this leaflet. See item 4.
- If after 3 days your child does not feel better or feels worse, you should consult a doctor.

What you will find on this leaflet
1. What is RHINXYL HA 0.5 mg/ml nasal spray solution and what is it used for?
2. What you should know before using RHINXYL HA 0.5 mg/ml nasal spray, solution
3. How to use RHINXYL HA 0.5 mg/ml nasal spray, solution
4. Possible side effects
5. How to store RHINXYL HA 0.5 mg/ml nasal spray, solution
6. Packaging contents and other information

1. What is RHINXYL HA 0.5 mg/ml nasal spray solution and what is it used for?

RHINXYL HA 0.5 mg/ml nasal spray, solution belongs to a group of medicines for the treatment of diseases of the nose, called sympathomimetics. It contains xylometazoline hydrochloride, which helps constrict blood capillaries in the nose, thereby reducing congestion of the nasal mucosa. RHINXYL HA 0.5 mg/ml nasal spray solution also contains hyaluronic acid (in the form of sodium hyaluronate), which protects and moisturises the nasal mucosa.

RHINXYL HA 0.5 mg/ml nasal spray, solution is used for:
- reduction of nasal mucosal congestion caused by inflammation of the nasal mucosa (rhinitis) or inflammation of the sinus mucosa (sinusitis).

RHINXYL HA 0.5 mg/ml nasal spray, solution is recommended for use in children aged 2 to 12 years.

2. What you should know before using RHINXYL HA 0.5 mg/ml nasal spray, solution

Do not use RHINXYL HA 0.5 mg/ml nasal spray, solution
- if your child is allergic to xylometazoline or any of the other ingredients of this medicine (listed in section 6)
- if your child has dry inflammation of the nasal mucosa(rhinitis sicca)
- if your child has undergone neurosurgery (transphenoidal surgery of the pituitary gland or any other neurosurgery involving exposure of the meninges)
- if your child has increased pressure inside the eye, especially narrow-angle glaucoma
- in infants and children under 2 years of age.

Warnings and precautions
Before using RHINXYL HA 0.5 mg/ml nasal spray, solution, ask your doctor or pharmacist:
- if your child is being treated with monoamine oxidase inhibitors (IMAO) (e.g. tranylcypromine and moclobemide, which are used to treat depression) or has used IMAOs within the last 2 weeks, tricyclic or tetracyclic antidepressants or other medicines that can increase blood pressure
- if your child is using medicines from the beta-blocker or alpha-blocker group (commonly used to lower blood pressure or in the treatment of benign prostatic hypertrophy (enlargement))
- if your child has severe cardiovascular disease (e.g. coronary heart disease, high blood pressure)
- if your child has a heart condition (e.g. prolonged QT syndrome)
- if your child has an adrenal tumour (phaeochromocytoma)
- if your child has an enlarged prostate
- if your child has porphyria (a metabolic disorder affecting the skin and/or central nervous system)
- if your child has a metabolic disorder (e.g. overactive thyroid gland, diabetes).

Long-term use of RHINXYL HA 0.5 mg/ml nasal spray, solution may lead to chronic swelling of the nasal mucosa and eventually atrophy (thinning) of the nasal mucosa. To prevent this reaction, the treatment period should be kept as short as possible (see section 3).
Long-term use and overdose should be avoided. Please ask your doctor about the duration of treatment in children.
If you think your child has a bacterial infection of the nose and sinuses, please consult your doctor, as such an infection needs to be treated properly.

Infants and children under 2 years of age
RHINXYL HA 0.5 mg/ml nasal spray, solution should not be used in infants and children under 2 years of age.

RHINXYL HA 0.5 mg/ml nasal spray, solution with other medicines
Ask your doctor or pharmacist if your child is taking, has recently taken, or may be taking any other medicines.

Concomitant use of RHINXYL HA 0.5 mg/ml nasal spray solution with monoamine oxidase inhibitors (IMAOs; e.g. tranylcypromine, moclobemide) or within 2 weeks of taking IMAOs, tricyclic or tetracyclic antidepressants, or other medicines that can increase blood pressure (e.g. doxapram, ergotamine, oxytocin), may cause increased blood pressure due to the effect of these medicines on the heart and blood vessels. Therefore, concomitant use with these medicines should be avoided.

This medicine should not be used concomitantly with medicines that lower blood pressure (e.g. methyldopa) because of the vasopressor effect of xylometazoline (i.e. blood pressure raising effect). Complex interactions may also occur when used with alpha- and beta-blocker medicines, causing low blood pressure or high blood pressure and rapid heartbeat (tachycardia) or slow heartbeat (bradycardia).

Pregnancy, breast-feeding and fertility
This concentration of RHINXYL HA 0.5 mg/ml nasal spray, solution is intended for use in children. This information is however valid for the active substance, xylometazoline hydrochloride.

If you are pregnant or breastfeeding, think you might be pregnant, or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

There are no adequate data on the use of xylometazoline hydrochloride in pregnant women. RHINXYL HA 0.5 mg/ml nasal spray, solution should therefore not be used during pregnancy.

This medicine should not be used during breastfeeding as it is not known whether xylometazoline hydrochloride is excreted in human milk.

Driving vehicles and operating machinery
The ability to drive or operate machinery is not expected to be reduced if the medicine is used as directed.

3. How to use RHINXYL HA 0.5 mg/ml nasal spray, solution

Always use this medicine exactly as described on this leaflet or as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you are not sure.

Doses
Children 2-12 years:
1 spray of RHINXYL HA 0.5 mg/ml nasal spray, solution in each nostril, up to 3 times a day.

RHINXYL HA 0.5 mg/ml nasal spray, solution should not be used for more than 5 days unless otherwise prescribed by your doctor. Use may be repeated if treatment has been discontinued for several days.

In the case of chronic colds, RHINXYL HA 0.5 mg/ml nasal spray solution should be used under medical supervision to prevent atrophy (thinning) of the child's nasal mucosa.

Do not use higher doses than recommended.

If after 3 days of continuous treatment, your child does not feel better or feels worse, you should consult a doctor.

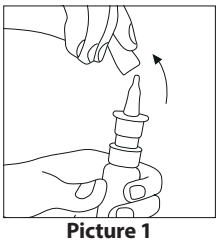
Use in infants and children under 2 years of age
RHINXYL HA 0.5 mg/ml nasal spray, solution should not be used in infants and children under 2 years of age.

Administration method

The spray should be administered while the child is upright. Therefore, it is best for young children to sit on your lap during application.

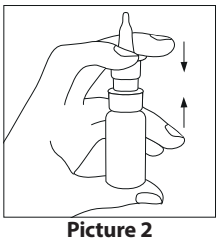
Blow your child's nose before using this medicine.

Remove the protective cover as shown in picture 1.

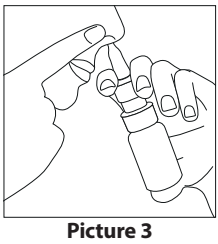

Picture 1

Hold the bottle between your index and middle finger, supporting the bottom with your thumb, as shown in picture 2. To spray, press the pump down.

Before the first application, it is necessary to spray in the air several times (5 times) to obtain an even dose.
If the medicine is not used for a few days, it should be sprayed into the air as a sample at least once to get an even dose.


Picture 2

Insert the tip of the dispenser pump into the nostril, as shown in picture 3 (do not spray under the nostril). Press the pump once and, at the same time, ask the child to breathe through the nose while you gently close the other nostril with the index finger of the other hand. Release the pump and remove it from the nostril.
Repeat this process in the other nostril.
After careful application, wipe the tip of the dispenser pump with a clean, dry paper towel and replace the protective cap.



Picture 3

For reasons of hygiene and to avoid transmission of infection, each spray bottle should only be used by one person.

If you use more RHINXYL HA 0.5 mg/ml nasal spray solution than you should
If your child (or someone else) has overdosed on this medicine, contact a doctor immediately, who will start the necessary treatment.

The following overdose symptoms may occur:
- dilated or shrunken pupils
- nausea and vomiting
- pallor, blue discoloration of the skin and lips
- increased body temperature, sweating or a drop in body temperature
- cardiovascular disorders, for example, a heart rhythm disorder such as too slow, too fast or irregular heartbeat, high or low blood pressure, circulatory collapse, cardiac arrest
- lung disorders (pulmonary oedema, breathing arrest (apnea))
- lethargy, drowsiness and coma
- anxiety, excitement, hallucinations, muscle spasms and seizures (convulsions).

Particularly in children, overdose can often be accompanied by convulsions and coma, slow heartbeat, breathing cessation (apnoea) and an increase in blood pressure, which may be followed by a drop in blood pressure.

If you forget to use RHINXYL HA 0.5 mg/ml nasal spray, solution
Do not use a double dose to make up for a missed dose, but continue using the medicine as directed.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although they do not occur in all people.

Stop using RHINXYL HA 0.5 mg/ml nasal spray solution immediately and seek medical attention if your child has any of the following symptoms (these may be signs of an allergic reaction):
- difficulty breathing or swallowing or swelling of the face, lips, tongue or throat
- severe itching of the skin, accompanied by a red rash or papules.

The following adverse reactions have been reported:

Frequent (can affect up to 1 in 10 people)
• headache
• temporary, mild symptoms of irritation, such as a burning or dry feeling in the lining of the nose and/or throat
• sneeze.

Less common (may affect up to 1 in 100 people)
• allergic reactions (skin rash, itching, swelling of the skin and mucous membranes)
• feeling of a "stuffy" nose (after the medicine has worn off)
• nosebleed.

Rare (may affect up to 1 in 1000 people)
• dizziness
• perception of heartbeat (palpitations)
• increased heart rate
• increase in blood pressure
• transient visual disturbances
• nausea.

Very rare(may affect up to 1 in 10,000 people)
• nervousness, restlessness
• difficulty falling asleep, insomnia
• drowsiness/moodiness (especially in children)
• hallucinations or seizures (especially in children)
• irregular heartbeat
• breathing stops (apnea) in young children or newborns.

Reporting adverse reactions
If your child has any side effects, ask your doctor or pharmacist. These include any possible side effects not mentioned on this leaflet. You can also report adverse reactions directly via the national reporting system, details of which are published on the website of the National Agency for Medicines and Medical Devices http://www.anm.ro/.
National Agency for Medicines and Medical Devices.
Str. Aviator Sanatescu no. 48, sector 1
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Tel:+4 0757 117 259
Fax: +4 0213 163 497
e-mail: adr@anm.ro.
By reporting adverse reactions, you can help provide additional information on the safety of this medicine.

5. How to store RHINXYL HA 0.5 mg/ml nasal spray, solution

Keep this medicine out of the sight and reach of children.
The medicine does not require special storage conditions.

Shelf life after first opening is 6 months.
Do not use this medicine after the expiry date written on the packaging after "EXP".

Do not dispose of any medicine in water or household waste. Ask your pharmacist how to dispose of medicines you no longer use.
These measures will help protect environment.

6. Packaging contents and other information

What RHINXYL HA 0.5 mg/ml nasal spray, solution contains
The active substance is xylometazoline hydrochloride. 1 ml of RHINXYL HA 0.5 mg/ml nasal spray, solution contains xylometazoline hydrochloride 0.5 mg. One spray (70 gl) contains xylometazoline hydrochloride 0.035 mg.
Excipients are purified seawater, potassium dihydrogen phosphate, sodium hyaluronate and purified water.

What RHINXYL HA 0.5 mg/ml nasal spray solution looks like and what it contains
Clear, colourless sterile solution. Contains no preservatives.
10 ml of solution in a white plastic bottle with dispenser pump, applicator tip and protective cap, packed in a box.

Marketing authorisation holder and manufacturer
Terapia SA
Str. Fabricii no. 124, Cluj Napoca, 400 632
Romania

Manufacturers
Jadran - Galenski laboratorij d.d.
Svilno 20, Rijeka, 51000
Croatia

Terapia SA
Str. Fabricii no. 124, Cluj Napoca, 400 632
Romania

This medicinal product is authorised in the Member States of the European Economic Area under the following trade names:
Latvia: Xylometazolini hydrochloridum Ranbaxy 0.5 mg/ml deguna aerosols, skîdums
Poland: Xylometazoline Coldact
Romania: RHINXYL HA 0.5 mg/ml nasal spray, solution

This leaflet was revised in April 2019.