

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

DriNasal Paediatric 0,025 % (Drops and Metered Spray)

Oxymetazoline hydrochloride

Read all of this leaflet carefully because it contains important information for you.

DriNasal Paediatric 0,025 % is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **DriNasal Paediatric 0,025 %** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **DriNasal Paediatric 0,025 %** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **DriNasal Paediatric 0,025 %** is and what it is used for.
2. What you need to know before you use **DriNasal Paediatric 0,025 %**.
3. How to use **DriNasal Paediatric 0,025 %**.
4. Possible side effects.
5. How to store **DriNasal Paediatric 0,025 %**.
6. Contents of the pack and other information.

1. What DRINASAL PAEDIATRIC 0,025 % is and what it is used for

DriNasal Paediatric 0,025 % is for application in the nose to give relief from:

- nasal congestion (blocked/stuffy nose, including colds)
- sinusitis (inflammation or swelling of the tissue lining the sinuses)
- allergic rhinitis (also called hay fever, is an allergic reaction that causes sneezing, congestion, itchy nose and watery eyes.)

DriNasal Paediatric 0,025 % is also used to assist in the treatment of middle ear infection

(inflammation of the area behind the eardrum).

2. What you need to know before you use DRINASAL PAEDIATRIC 0,025 %

Do not use DRINASAL PAEDIATRIC 0,025 %:

- if you are hypersensitive (allergic) to oxymetazoline hydrochloride, or any of the other ingredients of **DRINASAL PAEDIATRIC 0,025 %** (listed in section 6).
- if you have rhinitis sicca (abnormally dry nose, and/or inflamed skin or mucous membranes of your nostrils or scabs in your nose).
- if you have had an operation to remove your pituitary gland.

Warnings and precautions

Take special care with DRINASAL PAEDIATRIC 0,025 %

- If you are taking (or have taken during the last 2 weeks) monoamine oxidase inhibitors (MAO inhibitors) or tricyclic antidepressants (used in the treatment of depression), antiparkinson's medicines such as bromocriptine (used in the treatment of Parkinson's disease).
- If you are taking medicines that potentially increase blood pressure.
- If you suffer from increased eyeball-pressure (narrow-angle glaucoma).
- If you suffer from severe heart diseases (e.g. coronary heart disease ,angina, high blood pressure, cardiac asthma).
- If you suffer from phaeochromocytoma (tumor of adrenal gland tissue i.e. chromaffin cells).
- If you suffer from metabolic disorders (e.g. overactive thyroid, diabetes mellitus, porphyria).
- If you have enlargement of the prostate.

Long-term use and overdosage of **DRINASAL PAEDIATRIC 0,025 %** should be avoided.

Do not exceed the recommended dose.

If symptoms worsen or do not improve after 3 days, consult your doctor or pharmacist.

DRINASAL PAEDIATRIC 0,025 % should be used for a maximum of 5 consecutive days to avoid a rebound-effect and drug-induced rhinitis (recurrent inflammation/congestion of the nasal mucous membrane).

The effect of **DRINASAL PAEDIATRIC 0,025 %** may be reduced with long-term use or overdose. This may lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If long term use or overdose occurs, treatment should be discontinued immediately.

Continuous use may cause the tissue that lines the nose and the bone underneath to shrink down, causing blocked nose, swelling and irritation inside the nose.

Rebound effects and reduced effect should stop once use of **DRINASAL PAEDIATRIC 0,025 %** is discontinued.

Medical supervision is indicated in patients with chronic rhinitis.

Dosages higher than recommended may only be used under medical supervision.

Other medicines and DRINASAL PAEDIATRIC 0,025 %

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants used for the treatment of depression. **DRINASAL PAEDIATRIC 0,025 %** may cause high blood pressure if used during treatment with a MAOI or, tricyclic antidepressants (e.g. amitriptyline and imipramine).
- Medicines used for the treatment of high blood pressure.
- Medicines used to treat Parkinson's disease e.g. bromocriptine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Due to insufficient information available on the use of **DRINASAL PAEDIATRIC 0,025 %** during pregnancy and breastfeeding, it should only be used on the advice of a doctor.

Driving and using machines

DRINASAL PAEDIATRIC 0,025 % does not impair driving or the use of machinery.

However some possible side effects may occur with prolonged use of **DRINASAL PAEDIATRIC 0,025 %** which may have an effect on driving and using machinery.

3. How to use DRINASAL PAEDIATRIC 0,025 %

Do not share medicines prescribed for you with any other person.

Always take 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.

For children up to the age of 6 years, under adult supervision:

Metered Spray: 2 to 3 sprays in each nostril 2 to 3 times a day.

Drops: 2 to 3 drops of the liquid into each nostril 2 to 3 times a day.

DriNasal Paediatric 0,025 % should not be used for a period longer than 5 days.

Administration:

Metered Spray:

For best results keep both the head and spray bottle slightly tilted to the back.

1. Remove the cap by pulling.
2. With the middle and forefinger around the bottom of the nozzle and the thumb on the base of the bottle, press once to fill the pump mechanism completely.

3. Insert the nozzle of the spray loosely into the nostril, squeeze the pump spray 2 to 3 times and simultaneously sniff in to ensure an even distribution of the fine spray.
4. Repeat for other nostril.

Drops:

1. Fill glass dropper unit by placing the open end into the liquid and depressing the rubber teat.
2. Tilt the head back and instill 2 to 3 drops of the liquid into each nostril 2 to 3 times a day.

If you use more DRINASAL PAEDIATRIC 0,025 % than you should

Symptoms of an overdose may be:

Hypertension (high blood pressure), tachycardia (faster heartbeat), palpitations, cardiac dysrhythmia (an abnormal or irregular heartbeat), cardiac arrest (when the heart stops beating suddenly), sweating, agitation, convulsion, mydriasis (dilated pupils of the eyes), nausea, vomiting, cyanosis (when your skin, lips or nails turn blue due to a lack of oxygen in your blood), fever, spasms, drowsiness, paleness, miosis (constricted pupils of the eyes), decrease in body temperature, bradycardia (slow heart rate), shock-like hypotension (low blood pressure), apnoea (breathing stops), loss of consciousness and coma.

In children above 6 years, in particular, overdose often causes dominating central nervous effects with convulsions and coma, slow heart rate as well as high blood pressure, possibly followed by low blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use DRINASAL PAEDIATRIC 0,025 %

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

4. Possible side effects

DriNasal Paediatric 0,025 % can have side effects.

Not all side effects reported for **DriNasal Paediatric 0,025 %** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DriNasal Paediatric 0,025 %**, please consult your healthcare provider for advice.

If any of the following happens, stop using DriNasal Paediatric 0,025 % and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching
- Fits or seizures
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **DriNasal Paediatric 0,025 %**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following side effects:

- Fast, irregular or pounding heartbeat
- High blood pressure

These are all serious side effects. You may need urgent medical attention.

The following side effects have been frequently reported:

- Aqueous nasal secretions (runny nose), crusted nose

The following side effects have been reported less frequently:

- Rebound congestion (increase in runny or stuffy nose)
- Headache or light-headedness, nervousness, trembling
- Nausea

The following side effects have been reported but the frequency is unknown:

- Nasal discomfort (burning of the nasal mucosa), dryness (of the nose, mouth and throat), sneezing, swelling of the lining of the nasal mucosa, bleeding from the nostril
- Drowsiness, sleep or calm induced by medication, hallucinations, tremor, anxiety, restlessness, irritability, nervousness, convulsions, trouble sleeping
- Hypersensitivity (swelling, rash)
- Palpitations (a skipped, extra or irregular heartbeat), tachycardia (faster heartbeat), increased blood pressure
- Fatigue or tiredness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **DriNasal Paediatric 0,025 %**.

5. How to store DRINASAL PAEDIATRIC 0,025 %

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep the container tightly closed.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DriNasal Paediatric 0,025 % contains

The active substance is: Oxymetazoline hydrochloride 0,25 mg/ml.

The other ingredients are: Benzalkonium chloride (preservative), disodium EDTA, sodium hydroxide, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate hydrate.

What DRINASAL PAEDIATRIC 0,025 % looks like and contents of the pack

DriNasal Paediatric 0,025 % is a clear, colourless solution, with a faint odour.

10 ml Metered spray bottle:

brown glass bottle, containing 10 ml solution, with dispensing pump and cap.

10 ml Dropper bottle:

amber glass bottle, containing 10 ml solution, with glass pipette and cap.

Holder of Certificate of Registration

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