PATIENT INFORMATION LEAFLET FOR

OXYMIST 0,025 / 0,05 (Metered Nasal Spray)

SCHEDULING STATUS: S1

OXYMIST 0,025 / 0,05, Metered nasal spray

Oxymetazoline hydrochloride

Contains sugar: sorbitol 3,5 mg/1 mL

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

OXYMIST is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OXYMIST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OXYMIST with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What OXYMIST is and what it is used for
2. What you need to know before you use OXYMIST
3. How to use OXYMIST
4. Possible side effects
5. How to store OXYMIST
6. Contents of the pack and other information.

1. What OXYMIST is and what it is used for

OXYMIST (oxymetazoline) belongs to a class of medicines known as nasal decongestants.

It is used to relieve a blocked nose due to the common cold (acute rhinitis), sinusitis (inflammation or swelling of the tissue lining the sinuses), hay fever (allergic rhinitis), or as an add-on treatment for middle ear infection.

2. What you need to know before you use OXYMIST

Do not use OXYMIST:

- if you/your child are hypersensitive (allergic) to oxymetazoline hydrochloride, benzalkonium chloride (the preservative) or any of the other ingredients of OXYMIST (listed in **section 6**).
- if you/your child have rhinitis sicca (abnormally dry nose, and/or inflamed skin or mucous membranes of your nostrils or scabs in your nose).
- if you/your child recently had sinus surgery or nasal surgery, or had your pituitary gland removed.
- if you/your child are using other medicines for a blocked nose.
- if you/your child have been diagnosed with a tumour of the adrenal gland (phaeochromocytoma).

Do not give OXYMIST 0,05 to children below six years of age.

OXYMIST is considered unsafe in patients with porphyria.

Warnings and precautions

Take special care with OXYMIST:

- If you are taking (or have taken during the last two 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 Parkinsons's disease).
- 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 metabolic disorders (e.g. overactive thyroid, diabetes mellitus).
- If you have enlargement of the prostate.
- Problems with your liver.
- Problems with your kidneys.
- Narrowing of arteries.
- **Do not exceed the recommended dose.**
- If your/your child’s symptoms worsen or do not improve after 3 days, you should report to your doctor.
- OXYMIST should be used for a maximum of 5 consecutive days to avoid a rebound-effect and medicine-induced rhinitis (recurrent inflammation/congestion of the nasal mucous membrane).

Long-term use and overdosage of OXYMIST should be avoided.

The effect of OXYMIST 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 OXYMIST is discontinued.

OXYMIST contains benzalkonium chloride, which may cause irritation or swelling inside the nose, especially if used for a long time.

Medical supervision is indicated in patients with chronic rhinitis.

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

If you/your child develop any of the following, stop using OXYMIST and report to your doctor immediately:

- Hallucinations (seeing or hearing things that are not real).
- Restlessness.
- Sleep disturbances.

Take care not to spray OXYMIST into the eyes.

Children may be especially prone to systemic absorption of oxymetazoline with resulting side effects (see **"Possible side effects"**).

Other medicines and OXYMIST

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

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

- Monoamine oxidase inhibitors (MAOIs), or tricyclic antidepressants used for the treatment of depression. OXYMIST may cause high blood pressure if used during treatment with a MAOI or, tricyclic antidepressants (e.g. amitriptyline and imipramine).

- Beta-blockers for hypertension or a fast heart rate.
- Medicines used for the treatment of high blood pressure.
- Medicines used to treat Parkinsons disease e.g. bromocriptine.
- Medicines used to treat heart failure or abnormal heart rhythm e.g. digoxin.
- Medicines used to treat migraine e.g. ergot alkaloids, such as ergotamine or methysergide.

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 health care provider for advice before using OXYMIST.

Due to insufficient information available on the use of OXYMIST during pregnancy and breastfeeding, OXYMIST should only be used on the advice of a doctor.

OXYMIST 0,025 is indicated for paediatric use only.

Driving and using machines

Possible cardiovascular or central nervous system side effects may occur with long time use of OXYMIST which may have an effect on driving and using machinery.

OXYMIST may have influence on driving and operating machines considering reported side effects such as sleeplessness, nervousness, anxiety, restlessness, irritability, tremor (shaking), headache or light-headedness, dizziness, tiredness, sleepiness, sleep or calm induced by medication (sedation), seeing or hearing things that are not real, uncontrolled body moments, rebound low blood pressure and high blood pressure.

It is not always possible to predict to what extent OXYMIST may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which OXYMIST affects them.

3. How to use OXYMIST

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

Always use OXYMIST exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

OXYMIST 0,05 metered spray is indicated for adults and children over 6 years.

OXYMIST 0,025 metered spray is indicated for children up to the age of 6 years.

Do not use OXYMIST for more than 5 days (see **Warnings and precautions**").

Do not exceed the recommended dosage. If symptoms persist, consult a health care provider.

The usual dose is as follows:

OXYMIST 0,05:

Adults: 1 - 2 sprays into each nostril 2 – 3 times a day

Children over 6 years: 1 spray into each nostril 2 - 3 times a day.

OXYMIST 0,05 is not intended for children below the age of 6 years (see **Do not use OXYMIST**).

The single dose given for OXYMIST 0,05 must not be administered more than 3 times a day.

OXYMIST 0,025:

Children up to the age of 6 years: 2 to 3 sprays into each nostril 2 – 3 times a day.

How to use OXYMIST metered nasal spray:

For best results keep both the head and spray bottle in an upright position. Remove the cap by pulling and insert the nozzle of the spray loosely into the nostril with the middle and forefinger around the bottom of the nozzle and the thumb on the base of the bottle. Depress the spray mechanism (as shown in the diagram) thus producing a fine mist. Sniff in to ensure an even distribution of the spray. Withdraw from nostril and release the spray mechanism. Repeat for the other nostril.



Prevention of contamination:

- Wipe the tip of the applicator with a clean, damp tissue and replace the cap directly after use.
- Do not share your bottle of OXYMIST 0,05 with other people. Do not use one bottle of OXYMIST 0,025 for more than one child.

If you have the impression that the effect of OXYMIST is too strong or too weak, please speak to your doctor or pharmacist.

If you use more OXYMIST than you should

Overdosage may occur after nasal or accidental oral administration.

Symptoms of an overdose may be:

High blood pressure (hypertension), fast heartbeat, pounding heartbeat (palpitations), irregular heartbeat, the heart suddenly stops beating (cardiac arrest), sweating, agitation, convulsions

(fits), dilated pupils, nausea, vomiting, bluish coloured skin due to decreased oxygen in the blood (cyanosis), fever, spasms, blood circulation collapse, fluid in the lungs (pulmonary oedema), lung (respiratory) disorders, psychotic disorders, drowsiness, paleness, constricted pupils, decrease in body temperature, slow heartbeat, shock-like low blood pressure (hypotension), difficulty breathing (apnoea), loss of consciousness and coma.

In children above 6 years, in particular, overdose often causes mainly central nervous effects with convulsions (fits) and coma, slow heartbeat, difficulty breathing 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 centre.

If you forget to use OXYMIST

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

4. Possible side effects

OXYMIST can have side effects.

Not all side effects reported for OXYMIST are included in this leaflet. Should you/your child's general health worsen or if you experience any untoward effects while using OXYMIST, please consult your health care provider for advice.

If any of the following happens, stop using OXYMIST 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 (convulsions).
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to OXYMIST. 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:

- Fast, irregular or pounding heartbeat.
- High blood pressure.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Aqueous nasal secretions (runny nose), crusted nose.

Less frequent side effects:

- Nervousness, anxiety, irritability.
- Tremor (shaking), headache or light-headedness, nervousness, anxiety, irritability.
- Eye irritation, dryness, discomfort or redness.
- Discomfort, irritation, or dryness of the nose, mouth or throat, sneezing.
- Rebound congestion (increase in runny or stuffy nose).
- Nausea.

Side effects with unknown frequency:

- Trouble sleeping (insomnia), restlessness.
- Dizziness, sleepiness, sleep or calm induced by medication (sedation), (seeing or hearing things that are not real, uncontrolled body moments.

- Rebound low blood pressure.
- Nasal discomfort (burning or stinging of the nasal mucosa), irritation, rebound congestion, nasal dryness and sneezing, swelling of the lining of the nasal mucosa, bleeding from the nostril.
- 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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of OXYMIST.

5. How to store OXYMIST

Store at or below 25 °C.

Keep tightly closed.

Protect from light.

Store all medicines out of reach of children.

Keep in the outer carton until required for use.

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

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 OXYMIST contains

The active substance is oxymetazoline hydrochloride.

OXYMIST 0,025:	Each 1 mL of solution contains 0,25 mg oxymetazoline hydrochloride (0,025 % *m/v*)
OXYMIST 0,05:	Each 1 mL of solution contains 0,5 mg oxymetazoline hydrochloride (0,05 % *m/v*)

The other ingredients are benzalkonium chloride 0,01 % *m/v*, disodium hydrogen phosphate dihydrate, liquid sorbitol 70 %, sodium dihydrogen phosphate dihydrate (for pH adjustment), and water for injection.

What OXYMIST looks like and contents of the pack

Metered nasal spray.

OXYMIST 0,025:	Clear, colourless solution
OXYMIST 0,05:	Clear, colourless solution

OXYMIST 0,025:	10 mL tubular, USP Type 1, amber glass vial with a 20 mm neck finish with a polypropylene and polyethylene grade material crimp on nasal spray pump with a dip tube, and a white opaque polypropylene and polyethylene nasal adapter with an orifice tip, packed in an outer carton.
OXYMIST 0,05:	10 mL tubular, USP Type 1, amber glass vial with a 20 mm neck finish with a polypropylene and polyethylene grade material crimp on nasal spray pump with a dip tube, and a white opaque polypropylene and polyethylene nasal adapter with an orifice tip, packed in an outer carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and

included after approval.