PATIENT INFORMATION LEAFLET FOR ZYLOVIN

SCHEDULING STATUS

S1

ZYLOVIN 1 mg/mL nasal spray

Xylometazoline

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

ZYLOVIN is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to use ZYLOVIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ZYLOVIN 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 10 days.

What is in this leaflet

1. What ZYLOVIN is and what it is used for

2. What you need to know before you use ZYLOVIN

3. How to use ZYLOVIN

4. Possible side effects

5. How to store ZYLOVIN

6. Contents of the pack and other information

1. What ZYLOVIN is and what it is used for

ZYLOVIN contains xylometazoline hydrochloride, which belongs to a group of medicines known as arylalkyl imidazolines. It helps to open up your nasal passages by reducing excessive nasal secretions and returning swollen blood vessels to their normal size.

ZYLOVIN is indicated for application in your nose to give relief from nasal congestion (blocked nose, stuffy nose) caused by a cold, sinusitis (inflamed sinus), otitis media (inflammation of the middle ear) and/or to assist with rhinoscopy (a method used by doctors to look into your nose and throat).

2. What you need to know before you use ZYLOVIN

Do not use ZYLOVIN:

- If you are hypersensitive (allergic) to xylometazoline hydrochloride or any of the other ingredients of ZYLOVIN (listed in section 6).
- If you:
  - Have an overactive thyroid (hyperthyroidism),
  - Have an eye disorder known as narrow angle glaucoma (a condition where pressure builds up within your eye),
  - Have coronary heart disease (narrow or blocked arteries),
  - Have inflamed, crusty and blocked nasal passages (atrophic rhinitis),
  - Are being treated with medicines known as monoamine oxidase (MAO) inhibitors (used to treat depression) or 10 days after stopping treatment with these medicines.
- If you recently had neurosurgery (surgery performed on the nervous system, especially the brain and spinal cord).
- ZYLOVIN should not be used by children under the age of 12 years.

Warnings and precautions

Take special care with ZYLOVIN:

- If you experience symptoms such as insomnia, dizziness, tremor, changes in the way your heart beats or an increase in blood pressure.

- If you have high blood pressure.
- If you suffer from any heart problems.
- If you have high blood sugar (diabetes mellitus).
- If you suffer from nosebleeds.
- If you have been diagnosed with a tumour affecting your adrenal glands, known as phaeochromocytoma.
- If you are a male and you have an enlarged prostate gland.
- If you have a heart rhythm condition known as long QT syndrome.
- If you use ZYLOVIN for more than 10 continuous days, since prolonged or excessive use may cause your congestion symptoms (e.g. constant blocked or dry nose) to return.

Other medicines and ZYLOVIN

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 currently using:

- Monoamine oxidase inhibitors (MAOI) or other medicines used to treat depression (tricyclic or tetracyclic antidepressants), because these medicines may cause an increase in your blood pressure. You must wait at least 10 days before using ZYLOVIN after you stopped taking a monoamine oxidase inhibitor.

Pregnancy, breastfeeding and fertility

ZYLOVIN is not recommended during pregnancy since its use may lead to reduced circulation to the baby. It is not known whether ZYLOVIN is excreted in breast milk or if it affects your ability to have a baby.

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 ZYLOVIN.

Driving and using machines

ZYLOVIN may cause dizziness and visual disturbances. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ZYLOVIN affects you.

Important information about some of the ingredients of ZYLOVIN

ZYLOVIN contains 0,1 mg/mL of the preservative benzalkonium chloride. Benzalkonium chloride may cause
irritation or swelling inside the nose, especially if used for a long time.

3. How to use ZYLOVIN

Do not share medicines prescribed for you with any other person.
Always use ZYLOVIN exactly as indicated. You should check with your doctor or pharmacist if you are unsure.

The usual dose is to apply one spray into each nostril per application. A total of 3 applications a day is usually sufficient.

Instructions for use:

1. You should blow your nose before using ZYLOVIN.
2. Shake gently before each use.
3. Remove the protective cap.
4. Before the first application, you have to activate the pump of the metered-dose spray by performing several pumping motions, until an even spray appears in the air.

5. Insert the nozzle into your nostril and press once firmly on the spray head.



6. Breathe in at the same time, then withdraw the nozzle before releasing the pressure.
7. Repeat the action in the other nostril.
8. Replace the protective cap after use.
9. If you have not used the spray for 7 days (after the first use), then it will be necessary to activate the pump again by pressing the pump once.

Do not use ZYLOVIN for more than 10 continuous days.

If you have the impression that the effect of ZYLOVIN is too strong or too weak, tell your doctor or pharmacist.

If you use more ZYLOVIN than you should

If you use more ZYLOVIN than you should or if you accidentally ingest ZYLOVIN, you may experience symptoms such as severe dizziness, sweating, very low body temperature, headache, very slow heart rate, high or low blood pressure, slow and ineffective breathing, coma or fits and sometimes a foggy mind.

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 ZYLOVIN

If you have missed a dose, skip the missed dose and use ZYLOVIN at the next regularly scheduled time. Do not use a double dose to make up for the forgotten individual doses.

4. Possible side effects

ZYLOVIN can have side effects.

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

If any of the following happens, stop using ZYLOVIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

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

- Changes in the way your heart beats, such as beating faster or slower than normal, or skipping beats (palpitations).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- Nausea (feeling sick),
- Burning or irritation inside your nose.

Less frequent side effects:

- Transient visual disturbances,
- Skin rash.

Side effects with unknown frequency:

- Insomnia (inability to sleep), dizziness,
- Loss of smell, nosebleeds, rebound congestion (constant stuffy nose) after using ZYLOVIN for too long or too frequently, dry nose, a burning sensation in the nose and throat.

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 ZYLOVIN.

5. How to store ZYLOVIN

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not use for longer than one month after first opening the bottle.

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

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 ZYLOVIN contains:

The active substance is xylometazoline.

Each mL contains 1 mg xylometazoline.

The other ingredients are benzalkonium chloride, disodium edetate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, purified water. Benzalkonium chloride is added as a preservative.

What ZYLOVIN looks like and contents of the pack

Clear, colourless to almost colourless solution.

A 10 mL amber, transparent glass bottle with a white spray pump and protective cap.

The bottle is packed in an outer carton.

Each 10 mL bottle contains approximately 55 sprays.

Holder of certificate of registration

Lamar International (Pty) Ltd

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

South Africa

This leaflet was last revised in

Date of Registration: 19 July 2022

Registration number

51/16.1/0735