PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

OXYLIN® Liquifilm Sterile Ophthalmic Solution, **Oxymetazoline hydrochloride** 0,25 mg/ml, ophthalmic solution

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

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

- Keep this leaflet. You may need to read it again.
- Do not share OXYLIN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2-3 days.

1. WHAT OXYLIN CONTAINS

- The active substance is oxymetazoline hydrochloride 0,25 mg/ml
- The other ingredients are edetate disodium, Liquifilm (polyvinyl alcohol), povidone, sodium acetate, sodium chloride and purified water
- The preservative is benzalkonium chloride 0,004 % *m/v*

2. WHAT OXYLIN IS USED FOR

OXYLIN is an eye drop solution. It contains a medicine which constricts blood vessels and is used in the relief of redness of the eye(s) due to allergic or irritant conditions.

3. BEFORE YOU USE OXYLIN

Do not use OXYLIN:

- If you are hypersensitive (allergic) to oxymetazoline hydrochloride or any of the other ingredients of OXYLIN;
- If you are taking monoamine oxidase (MAO) inhibitors (found in some anti-depressants), or within 14 days of stopping such treatment;
- If you suffer from narrow or closed angle glaucoma;
- Not recommended for use in children.

Take special care with OXYLIN:

- If using OXYLIN repeatedly or for a prolonged time;
- If you have an extensive eye surface disease;
- If you suffer from heart disease, high blood pressure, high blood sugar (diabetes mellitus), overactivity of thyroid;
- If you suffer from prostatic enlargement;
- If you have a red, inflamed eye;
- If you wear soft contact lenses (see “Important information about some of the ingredients of OXYLIN”).

If you think any of these points apply to you, do not use OXYLIN until you have talked to your doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using OXYLIN.

Driving and using machinery

Your sight may become blurred for a short time just after using OXYLIN. You should not drive or use machines until your sight is clear again.

Important information about some of the ingredients in OXYLIN

Avoid contact with soft contact lenses. If you wear soft (hydrophilic) contact lenses you should remove them before using OXYLIN and wait at least 15 minutes before putting your lenses back in.

OXYLIN contains a preservative, called benzalkonium chloride, which can cause eye irritation and discolour soft contact lenses.

Using other medicines with OXYLIN

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

If you are taking medicine to treat high blood pressure or depression, talk to you doctor before using OXYLIN.

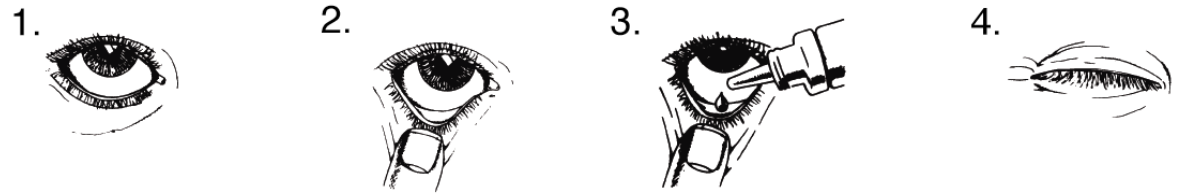
4. HOW TO USE OXYLIN

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

The usual dose is one to two drops in the eye(s) two to four times a day.

Instructions for use:

Apply your eye drops in the following way:



1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull down the lower eyelid until there is a small pocket.
3. Turn the bottle upside down and squeeze it to release one to two drops into each eye that needs treatment.
4. Let go of the lower lid and close your eye for 30 seconds.
5. If a drop misses your eye, try again.

To avoid eye injury or contamination, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle straight after you have used it. The use of the bottle by more than one person may spread infection.

If you use more OXYLIN than you should

If you accidentally place too many drops in your eye(s), wash with water. If, by accident, anyone drinks OXYLIN, drink fluids to dilute and consult your doctor or pharmacist.

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 OXYLIN

If you forget a dose, apply a dose as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then use your next dose at

the usual time and continue with your normal routine. Do not use a double dose to make up for a forgotten dose.

5. POSSIBLE SIDE EFFECTS

OXYLIN can have side effects. Not all side effects reported for OXYLIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OXYLIN, please consult your doctor, pharmacist or other healthcare provider for advice.

The following side effects may be seen with OXYLIN:

- Eye irritation;
- Pupils become larger or smaller;
- Rebound congestion;
- Eye pain;
- Increased eye pressure.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist. You can report side effect to SAHPRA via “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publication: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of OXYLIN.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

6. STORING AND DISPOSING OF OXYLIN

- Store at or below 25 °C.
- Do not use more than 30 days after first opening.

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the bottle and the box.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF OXYLIN

OXYLIN is supplied in sterile plastic dropper bottles containing 5 ml or 15 ml solution.

8. IDENTIFICATION OF OXYLIN

OXYLIN is a clear, colourless to slightly yellow solution.

9. REGISTRATION NUMBER

V/15.4/41

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

AbbVie (Pty) Ltd

Building 7

Waterfall Corporate Campus

74 Waterfall Drive

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11. DATE OF PUBLICATION

Date of registration: 26 September 1988

Date of most recent patient information leaflet as approved by Council: 21 April 2023

For the professional information please email medicalinfo.za@abbvie.com

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