

Minims® Oxybuprocaine Hydrochloride

0.4% w/v Eye Drops, solution

Oxybuprocaine hydrochloride

Read all this leaflet carefully **before** you start using your medicine. It contains a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Remember this medicine is for you. Do not give it to someone else.

In this leaflet:

1. What Minims® Oxybuprocaine Hydrochloride eye drops are and what they are used for
2. Before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Further information

1. What Minims® Oxybuprocaine Hydrochloride eye drops are and what they are used for

Minims® Oxybuprocaine Hydrochloride contains an anaesthetic. It is used to numb the surface of the eye temporarily. Your doctor or eye specialist will use it:

- to examine your eye without it being painful,
- to measure the pressure inside your eye,
- to perform minor operations such as the removal of stitches and foreign bodies,
- for the fitting of contact lenses,

This medicine is indicated for children, adults and the elderly.

2. Before you use your eye drops

Do not use these drops if

- you are allergic to the active substance (oxybuprocaine hydrochloride) or any of the other ingredients (refer to the end of this leaflet).
- you are using at the same time as Minims® Oxybuprocaine Hydrochloride other eye drops containing chlorhexidine acetate as a preservative.

Take special care

- If you have had an allergic reaction to other local anaesthetics in the past. Inform your doctor or eye specialist.
- When your eye has been numbed it is important not to rub it and to keep it free of dust and bacterial contamination. Your doctor or eye specialist will make sure that your eye is properly protected.
- If you have an inflamed eye, as red eyes greatly increase the passage into the blood stream through the surface of the eyes. Your eye drops are not intended for long term use. Frequent use of local anaesthetic in the eye over long periods of time may severely affect your eyesight.

If you are pregnant, may be pregnant, or are breastfeeding

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops.

There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

3. How to use your eye drops

The drops are in special single use “Minims” units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Dosage

The amount of anaesthetic used will vary, depending on the procedure decided by your doctor or eye specialist:

- One drop of solution is enough to allow your doctor or eye specialist to measure the pressure inside your eye.
- Two drops, one and a half minutes apart is enough to allow contact lenses to be fitted.
- Three drops at one and a half minute intervals is enough to allow minor operations to be performed.

Method of administration

The doctor or eye specialist will put the drops in your eye for you. You may be asked to press on the inner corners of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk. Your eye will remain numb for about one hour, depending on how many drops you received. Avoid touching the eye until the anaesthetic has worn off.

If you have other eye drops to instill, you should wait at least 15 minutes before administering them.

If you use more Minims® Oxybuprocaine Hydrochloride than you should, an overdose is very unlikely to occur.

If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Minims® Oxybuprocaine Hydrochloride may sting when the drops are first put in and your vision may become blurred. Eye irritation may also occur. This will gradually wear off.

Other side effects

Not known: frequency cannot be estimated from the available data.

Minims Oxybuprocaine Hydrochloride does not usually cause side effects, but allergic reactions (including anaphylactic shock have occasionally occurred.

The symptoms of anaphylaxis/anaphylactic shock (severe allergic reactions) are difficulty breathing or swallowing, swelling of the face, lips, throat or tongue and severe skin rash. You should inform your doctor immediately if you get any of these symptoms. The symptoms of an allergic reaction are redness, swelling and itching of the eyes.

This medicine can affect the cornea (the transparent membrane covering the iris and the pupil of the eye), causing intense discomfort, pain, redness, sensitivity to light or loss of visual acuity (the clarity or sharpness of vision).

Red, swollen or itchy eyes, burning or tearing of the eyes, itchy eyelids, foreign body sensation may also occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme - Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your eye drops

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month. Do not store above 25°C. Do not freeze. Store in the original package to protect from light.

The drops are in special single use "Minims" units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What do your eye drops contain

- The active ingredient oxybuprocaine hydrochloride. Each unit contains approximately 0.5 ml eye drops solution of oxybuprocaine hydrochloride 0.4% w/v (2 mg).
- The other ingredients are hydrochloric acid (for pH adjustment) and purified water. This medicine does not contain a preservative as it is a sterile single use unit.

Contents of the pack

Each carton contains 20 units.

Marketing Authorisation Holders:

Bausch & Lomb UK Ltd.
106 London Road, Kingston-upon-Thames,
KT2 6TN - UK Tel: +44 (0)20 8781 2900 /
Fax: +44 (0)20 8781 2901

BAUSCH + LOMB IRELAND LIMITED

3013 Lake Drive
Citywest Business Campus
Dublin 24, D24PPT3
Ireland

Manufacturer:

Laboratoire Chauvin - Z.I.Ripotier - 07200
Aubenas - France

Marketing Authorisation Number:

Minims® Oxybuprocaine Hydrochloride
0.4% w/v : PL 03468/0053 (UK) ;
PA23259/015/001 (Ireland)

DATE OF PREPARATION: June 2022