

**BAUSCH + LOMB**

Minims® Oxybuprocaine Hydrochloride 0.4% w/v Eye Drops, solution

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

- Minims® Oxybuprocaine Hydrochloride may sting when the drops are first put in and your vision may become blurred. This will gradually wear off. Minims® Oxybuprocaine Hydrochloride does not usually cause side effects, but allergic reactions have occasionally occurred. The symptoms of an allergic reaction are redness, swelling and itching of the eyes.
- Toxic effects can affect the cornea (the transparent membrane covering the iris and pupil of the eye), causing intense discomfort, pain, redness, sensitivity to light or loss of visual acuity.

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Holder

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

Manufacturer:

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

To report any side effect(s)

• Saudi Arabia

National Pharmacovigilance center

Fax: +966-11-205-7662
Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
Toll free phone: 8002490000
E-mail: npc.drug@sfd.gov.sa
Website: www.sfd.gov.sa/npc

• United Arab of Emirates:

Tel: 80011111
E-mail: pv@moh.gov.ae
P.O. box: 1853 Dubai

• Other countries:

Please contact the relevant competent authority.

Council of Arab Health Ministers

- This is a medicament
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are the experts in medicines, their benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
 - Keep all medicaments out of reach of children.

DATE OF PREPARATION: August 2014

Minims is a trademark of Bausch & Lomb Incorporated or its affiliates.

© Bausch & Lomb Incorporated.