

Package leaflet: Information for the patient

Oxybuprocaine hydrochloride 4 mg/ml eye drops, solution in single-dose container oxybuprocaine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Oxybuprocaine hydrochloride is and what it is used for

Oxybuprocaine hydrochloride contains the active substance oxybuprocaine hydrochloride, a local anaesthetic, which is particularly suitable for 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,

Oxybuprocaine hydrochloride is indicated for the treatment of adults, adolescents and children.

The medicinal product can only be used for a short period of time.

2. What you need to know before you use Oxybuprocaine hydrochloride

Do not use Oxybuprocaine hydrochloride

- if you are allergic to oxybuprocaine hydrochloride or any of the other ingredients of this medicine (see section 6).
- If you are using at the same time as 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.

Other medicines and Oxybuprocaine hydrochloride

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Oxybuprocaine hydrochloride is not compatible with:

- silver nitrate (bactericide);
- mercury salts (disinfectants);
- alkaline substances (e.g. detergents).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

The use of oxybuprocaine hydrochloride during pregnancy and lactation has not been adequately studied. Your doctor will assess whether the benefits to you clearly outweigh the risks to the foetus/child before giving you Oxybuprocaine hydrochloride .

Driving and using machines

Wait until the anaesthetic effect of Oxybuprocaine hydrochloride has worn off before driving vehicles or using machines.

Oxybuprocaine hydrochloride contains boric acid

Do not administer to children under 2 years of age without medical advice, as this medicine contains boron and may impair fertility in the future, if it is used more frequently than medically advised.

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.

3. How to use Oxybuprocaine hydrochloride

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 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxybuprocaine hydrochloride

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.
Do not freeze.

For single use only.

After the first opening of the sachet: use the single-dose containers within 3 months.
After the first opening of the single-dose container: use immediately and discard the single-dose container even if partially used.

Do not use this medicine if you notice changes in the colour of the solution or the appearance of a sediment (visible solid particles).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxybuprocaine hydrochloride contains

- The active substance is oxybuprocaine hydrochloride. Each ml of solution contains 4.0 mg of oxybuprocaine hydrochloride.
- The other ingredients are: boric acid, purified water.

What Oxybuprocaine hydrochloride looks like and contents of the pack

Eye drops of 20 or 30 unit single-dose containers in neutral colour, divided in 2 or 3 strips of 10 containers, are contained in PET/Al/PE pouches (1 strip in each pouch) and then in a suitable box, together with the leaflet.

Each carton box contains 20 or 30 single-dose polyethylene containers containing 0.5 ml of solution. Each single-dose container contains 12 drops.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

MARKETING AUTHORISATION HOLDER:

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