

anestocil[®]

Oxybuprocaine hydrochloride 0.4%

4 mg/ml eye drops, solution

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Anestocil is and what it is used for
2. Before you use Anestocil
3. How to use Anestocil
4. Possible side effects
5. How to store Anestocil
6. Further information

1. WHAT ANESTOCIL IS AND WHAT IT IS USED FOR

Anestocil eye drops, solution contains oxybuprocaine hydrochloride at 4 mg/ml, with an osmolality and pH value appropriate.

Anestocil has superficial anaesthetic action of the cornea.

Anestocil is indicated for superficial anaesthesia, when necessary, in certain medical interventions, such as: tonometry, examinations for contact lenses and foreign body removal from the cornea and the conjunctiva.

2. BEFORE YOU USE ANESTOCIL

Do not use Anestocil

- If you are allergic (hypersensitive) to the active substance (oxybuprocaine hydrochloride) or to any of the other ingredients of Anestocil;
- For improving the tolerance to contact lenses.

Take special care with Anestocil

- Anaesthetic eye drops have no healing action; thus, in case they are applied without medical indication, with the intention of relieving pain in the eyeball, such administration shall not exceed two days without consulting an ophthalmologist;
- The indiscriminate use of this eye drops solution may cause severe lesions in the cornea and irreversible changes in the visual perception;
- This eye drops should not be used to relieve pain in the eyeball, without previous diagnostic from the ophthalmologist, because it can hide or aggravate cornea lesions;
- It should be used with caution in patients with allergy and hyperthyroidism;
- It should not be used by young children without medical indication.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

No interactions were reported with Anestocil.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

No trials were performed in these situations; therefore, this eye drops should not be used during pregnancy or lactation.

3. HOW TO USE ANESTOCIL

Always use Anestocil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose should be established by medical specialist according to the needs of each case. The usual dose for all ages is 1 to 2 drops, two minutes before the medical intervention.

It should not be used by young children without medical indication.

Apply the eye drops in the conjunctival sac (inside of the lower eyelid, taking care not to touch the eye or eyelashes with the dropper or bottle).

Like other eye drops, use Anestocil within 28 days, after first opening the bottle.

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

4. POSSIBLE SIDE EFFECTS

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

In the moment of the instillation, there may be a feeling of burning or irritation, but it does not represent a problem, besides the temporary eye discomfort.

At the ocular level: conjunctivitis, corneal oedema, corneal ulcer, delay of the corneal healing and of punctate keratitis.

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

5. HOW TO STORE ANESTOCIL

Keep out of the reach and sight of children.

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

Do not store above 25°C. Store in the original package protected from light and moisture.

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 Anestocil contains

- The active substance is Oxybuprocaine hydrochloride;
- The other ingredients are: sodium chloride, phenylmercuric nitrate and highly purified water.

What Anestocil looks like and contents of the pack

Anestocil eye drops, solution is supplied sterile in opaque white LDPE bottles with transparent dropper insert and opaque white HDPE caps with tamper-proof closure. Each bottle contains 10 ml of Anestocil eye drops, solution.

Marketing Authorisation Holder and Manufacturer

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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 experts in medicines their benefits and risks.
- Do not by your-self 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 the children.

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Union of Arab Pharmacists

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