This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in June 2024

LOCALIN®

1. Name of the medicinal product

LOCALIN sterile ophthalmic drops

2. Qualitative and quantitative composition

A clear, colorless, sterile eye drops, available as a 0.4% w/v solution of Oxybuprocaine Hydrochloride Ph.Eur.

3. Pharmaceutical form

Sterile eye drops

4. Clinical particulars

4.1 Therapeutic indications

As a topical ocular anaesthetic.

4.2 Posology and method of administration

Adults (including the Elderly) and Children

This information is intended for use by health professionals.

As a topical ocular anesthetic.

Localin must be used only by physicians Eye doctors. It is for the use of adults (including the Elderly) and Children

One drop is sufficient when dropped into the conjunctival sac to anaesthetise the surface of the eye to allow tonometry after one minute. A further drop after 90 seconds provides adequate anaesthesia for the fitting of contact lenses. Three drops at 90 second intervals provide sufficient anaesthesia for a foreign body to be removed from the corneal epithelium or for incision of a meibomian cyst through the conjunctiva. Corneal sensitivity is normal again after about one hour.

Instill dropwise into the eye according to the recommended dosage.

Directions for use:

1. In order to prevent contamination, do not let the tip of the bottle touch any surface (including the eye itself). Keep the bottle well closed.
2. The bottle of eye drops may not be full; this is designed to allow better control of the drip rate.
3. How to use the drops: First, wash your hands. Tilt your head back. Using your index finger, pull your lower lid down to create a “pocket”. Drip the medicine into the “pocket” formed. Gently close your eyes. Do not blink. Keep your eyes closed for 1 to 2 minutes.
4. After using the medicine, wash your hands thoroughly in order to remove any residual medicine.
5. In order to avoid spreading infection, do not use the medicine bottle for more than one person.

4.3 Contraindications

Not to be used in patients with a known hypersensitivity to the product.

4.4 Special warnings and precautions for use

Transient stinging and blurring of vision may occur on instillation.

The anaesthetised eye should be protected from dust and bacterial contamination.

When applied to the conjunctiva, oxybuprocaine is less irritant than amethocaine in normal concentrations.

The cornea may be damaged by prolonged application of anaesthetic eye drops.

4.5 Interaction with other medicinal products and other forms of interaction
None stated.

4.6 Pregnancy fertility and lactation
This product should not be used in pregnancy or lactation, unless considered essential by the physician.

4.7 Effects on ability to drive and use machines.
Patients should be advised not to drive or operate hazardous machinery until normal vision is restored.

4.8 Undesirable effects
The side effects are listed in the following frequencies: Very common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 1/10,000, < 1/1,000); Very rare (< 1/10,000); Not known (cannot be estimated from the current available data).

In very rare cases, uncontrolled use, i.e. long-term and/or too frequent use, may result in keratopathy, hypopyon, or central corneal erosion including central scarring.

Corneal perforation may also be possible.

Transient irritation, stinging and blurring of vision may occur on instillation.

In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances, anaphylactic shock).

Table 1.

Eye disorders	
Not known:	Eye pain, eye irritation, blurred vision, keratopathy, hypopyon, corneal erosion, corneal perforation, eye allergy, allergic blepharitis.
Immune system disorders:	
Not known:	Hypersensitivity, anaphylactic reaction/shock.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/

4.9 Overdose
Overdose following the recommended use is unlikely.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Oxybuprocaine hydrochloride is used as a local anaesthetic as it reversibly blocks the propagation and conduction of nerve impulses along nerve axons.

5.2 Pharmacokinetic properties
The rate of loss of local anaesthetics through tearflow is very high as they induce an initial stinging reaction which stimulates reflex lacrimation and leads to dilution of the drugs. It is thought that this is responsible for the very short duration of maximum effect of local anaesthetics. The non-ionised base of oxybuprocaine is rapidly absorbed from the pre-corneal tear film by the lipophilic corneal epithelium. The drug then passes into the corneal stroma and from there into the anterior chamber where it is carried away by the aqueous flow and diffuses into the blood circulation in the anterior uvea. As with other ester type local anaesthetics, oxybuprocaine is probably rapidly metabolised by plasma cholinesterases (and also by esterases in the liver).

5.3 Preclinical safety data
No adverse safety issues were detected during the development of this formulation. The active ingredient is well established in clinical ophthalmology.

6. Pharmaceutical particulars
6.1 List of excipients
Boric Acid, Chlorbutanol, Disodium Edetate, Purified Water

6.2 Incompatibilities
None known

6.3 Shelf life
Unopened: 18 months

6.4 Special precautions for storage
Store below 25°C. Do not freeze. Protect from light.

6.5 Nature and contents of container
A sealed conical shaped polypropylene Bottle fitted with a twist cap and dropper. Each bottle holds approximately 15 ml of solution.

6.6 Special precautions for disposal and other handling
None

7. Marketing authorization holder

Fischer pharmaceuticals Ltd

Bar Yochai 9th Bnei Brak,

Israel

8. Marketing authorization number(s)
051 87 23942 00

9. Date of first authorization/renewal of the authorization
Date of first authorization: 02/1968

10. Date of revision of the text
June 2024

The expiry date of the product is indicated on the packaging materials