SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Elipa 5 mg/ml, eye drops, solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketorolac tromethamine 5 mg/ml.

Excipient(s) with known effect:

Benzalkonium chloride (50% solution) – 0.1 mg/ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Elipa is presented as eye drops, solution in a 10 ml container.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Elipa is indicated in all inflammatory situations in ophthalmology where it is useful to inhibit prostaglandins biosynthesis, namely controlling pain and preoperative and posttraumatic inflammatory reaction. It is also indicated in the inhibition of the intraoperative miosis and preventing inflammation and cystic macular edema after cataract surgery. Due to its anti-inflammatory effect, it is equally indicated in the symptomatic treatment of allergic conjunctivitis, namely seasonal allergic conjunctivitis.

4.2 Posology and method of administration

Posology

Preparation for surgery: 1 drop every half an hour on the eyeball during the two hours prior to the surgical intervention (total of 4 drops).

Postoperative period: Medical criteria shall define the posology for a period of 3 weeks (recommended period of time for using this drug).

Other indications: The recommended average posology is 1 drop on the eyeball 4 times a day. The treatment should not be longer than one week, unless the doctor thinks otherwise.

The efficacy and safety of this medicinal product have not yet been studied in paediatric patients, aged below 12 years.

4.3 Contraindications

Hypersensitivity to the active substance (ketorolac tromethamine) or to any of the excipients listed in section 6.1.

It is possible that there is crossed sensitivity with acetylsalicylic acid and other non-steroidal anti-inflammatory drugs. Elipa is contraindicated in hypersensitive patients that have previously shown sensitivity to these drugs.

Elipa should not be used simultaneously with contact lenses.

4.4 Special warnings and precautions for use

Elipa should not be used simultaneously with contact lenses. Contact lenses users should use glasses during treatment.

After first opening, you should use Elipa within 28 days.

It is advisable that Elipa is used with caution in patients that have hemorrhagic tendency or that are being subject to anti-coagulant treatment.

This medicine contains 0.05 mg of benzalkonium chloride in each ml of solution. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use any other ophthalmic medicinal product without asking your doctor. Ask your doctor for advice before starting or withdrawing medicines or products for ocular application.

Elipa has been well tolerated when associated with ophthalmic and systemic medicines such as antibiotics, sedatives, beta-blockers, carbonic anhydrase inhibitors, miotics, mydriatics, cycloplegics and corticosteroids.
Use under monitoring in patients that have hemorrhagic tendency or that are being subject to anti-coagulant treatment.

4.6 Pregnancy and lactation

The safety of its use in pregnant women has not been established. Elipa is not recommended to breastfeeding women. Ketorolac tromethamine is secreted by breast milk after systemic administration.
Inform your doctor if you are pregnant, trying to get pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

No effects were observed.

4.8 Undesirable effects

There are very rare reports of prickling and burning in the eyes and eyelids in the moment of instillation, namely in patients that suffer from allergic conjunctivitis. There are also reports of allergic reactions, ocular irritation, superficial ocular infections and superficial keratitis.
After instillation, the vision may be temporarily blurry.
Other possible undesirable effects include flu symptoms, nausea, vomiting and haemorrhages.
If any of these side effects get serious or if they remain for a long period, or if you notice any side effects not listed in this leaflet, you should tell your doctor.

4.9 Overdose

No case of overdose has been reported with Elipa.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: **S01BC05** KETOROLAC

Ketorolac tromethamine is a non-steroidal anti-inflammatory that shows analgesic, anti-inflammatory and antipyretic activity when it is administrated systemically. The mechanism that induces such actions is, in part, due to the ability to inhibit the biosynthesis of prostaglandins. Ketorolac tromethamine's ocular administration reduces the levels of prostaglandin EB_{2B} in the aqueous humor.

Prostaglandins induce a certain type of ocular inflammation, since its presence causes vasodilatation and increase of the vascular permeability, leukotaxis, increase of the intra-ocular tonus and rupture of the blood-aqueous fluid barrier. By fostering the constriction of the iris sphincter, the prostaglandins are responsible for the pupillary miotic response during ocular surgery.

5.2 Pharmacokinetic properties

Elipa's action is essentially local.

5.3 Preclinical safety data

Ketorolac tromethamine is a substance that, from a toxicological perspective, may be used on humans and does not show any issue that requires special measures or that prevent it from being used as a therapeutic agent.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium chloride, disodium edetate, benzalkonium chloride, water for injections.

6.2 Incompatibilities

Benzalkonium chloride is not compatible with aluminium, anionic surfactant, fluorescein, hydrogen peroxide, hydroxypropylmethylcellulose, iodine compounds, lanoline, nitrates, highly concentrated non-ionic surfactants, permanganates, proteins, salicylates, silver salt, sulphonamides, zinc oxide, some rubber compounds, some plastic compounds and soft contact lenses.

Water for injections is not compatible with substances that hydrolyse easily, alkaline metals and their oxides, several acetates anhydrous salts and certain organic materials.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30ºC

6.5 Nature and contents of container

Elipa, eye drops, comes in a 10 ml LD-polyethylene bottle, with a LD-polyethylene sealed dropper tip, and a HD-polyethylene cap. The set is previously sterilised by gamma rays. After being filled, the bottles are packed into duly printed cartons with the respective package leaflet.

6.6 Special precautions for disposal and other handling

Open the container's cap and slightly press it, dispensing the liquid drop by drop in the recommended dosage.

No special requirements on the disposal of this medicine.

7. MARKETING AUTHORISATION HOLDER

Laboratório Edol – Produtos Farmacêuticos S.A.

Av. 25 de Abril, 6-6A

2795-225 Linda-a-Velha - Portugal

8. MARKETING AUTHORISATION NUMBER(S)

06785/08257/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 24, 2021

10. DATE OF REVISION OF THE TEXT

10/2019