

FLUOROBIOPTAL Eye Drops

Dexamethasone 0.2gm
Chloramphenicol 0.5gm
STERILE OPHTHALMIC SUSPENSION

فلوروبائیوپٹل
آنکھوں کے لئے قطرے جراثیم سے پاک

Composition:

Each 100ml contains:
Chloramphenicol 0.5gm. Dexamethasone 0.2gm.

Indications:

Acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature, Infections of the anterior uvea iritis, iridocyclitis. Scleritis, episcleritis and myositis sympathetic ophthalmia. Post-operative management of cataract, glaucoma and strabismus. Fluorobioptal is indicated if the infective agent is resistant to other antibiotics.

Contraindications:

Hypersensitivity to the ingredients.
Injuries and ulcerous processes of the cornea, Herpes simplex and other virus conditions, Mycosis; Glaucoma.
Severe blood disorders due to bone marrow depression and hepatic dysfunctions;
Newborn babies:
Family history of bone marrow depression.

Dosage and administration:

Insert one drop into the conjunctival sac 3-5 times per day. In acute cases insert 1 drop every hour or use as per Physician's advice. Care should be taken not to discontinue therapy prematurely.

Precautions:

Corticosteroids could mask, activate or aggravate an infection in the eye. As with all corticosteroids, the dosage for babies and infants under 2 years of age should be selected with caution. Fluorobioptal should not be used for more than 10 days. If no improvement is seen after 7-8 days of treatment, other therapeutic measures should be considered. Fluorobioptal therapy associated with a potential risk of aplastic anemia or other hematodyscrasias. A careful risk/benefit evaluation should therefore be made in each individual case. The product should only be used where alternative therapies are ineffective and/or contraindicated.

Patients wearing contact lenses should take the medication when the lenses are not worn.

Pregnancy and lactation:

Pregnancy category: C
Animal experiment with Fluorobioptal have shown adverse effects on the fetus. However, controlled human studies are available. Fluorobioptal should not be prescribed to pregnant patients, to new-born infants, nor during lactation.

Adverse reactions:

A slight sense of burning may occur for a short time after instillation of the product into the eye, without affecting the success of the treatment. The patient may notice a bitter taste shortly after instillation. When used for several weeks, a reversible increase in eye pressure is

possible in predisposed patients. Regular pressure checks are advisable. Partially irreversible hematodyscrasia (aplastic anemia, pancytopenia, leucopenia, thrombocytopenia, agranulocytosis) has been observed in isolated cases following topical use of Fluorobioptal. However, the severity and the moment of manifestation of such partially irreversible and lethal effects did not correlate with the commonly elevated dosage used in these studies. Long term treatment with topical corticosteroids may cause adverse systemic effects especially in children, rare cases of corneal softening and cataracts have been reported.

Overdose:

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce absorption should be taken, there is no specific antidote.

Storage and use:

Store between 15 to 25°C.

Close the bottle immediately after Use. Do not use for longer than one month after opening the bottle. It is advisable to destroy any medicament remaining after the end of the treatment. Fluorobioptal can be used up to the expiry date printed on the pack if the pack is unopened.

Excipients

Boric acid
HPMC
Sodium Borate
Sodium Citrate dehydrate
Sodium metabisulfite

Preservative:

Thiomersal

Shake well before use.

Presentation:

Dropper, bottle of 5 ml

مقدار اور طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق۔

۱۵ سے ۲۵ ڈگری سینٹی گریڈ کے درمیان رکھیں۔

روشنی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

بوتل کھولنے کے بعد ۳۰ دن سے زائد

استعمال نہ کریں۔

Manufactured by:

Elko Organization (Pvt.) Ltd.
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Karachi, Pakistan.

