

Oculotect® fluid sine

Polyvidone 5%

Eye drops / Ophthalmic solution

Artificial tears

Composition:

Each ml contains: Polyvidone 50 mg (mean molecular mass 29,000), Boric acid 2.0 mg, Sodium chloride 5.4 mg, Sodium lactate 0.2 mg, Potassium chloride 1.5 mg, Calcium chloride 0.15 mg, Magnesium chloride 0.2 mg, Water for injections to 1 ml. Preservative free.

Pharmaceutical form:

Eye drops, in single-dose pipettes.

Preservative free.

Properties and actions:

Oculotect® fluid sine eye drops are an almost colourless, clear, preservative free aqueous solution administered in the form of drops. After topical application Oculotect® fluid sine eye drops spreads rapidly over the conjunctiva and cornea forming a lubricating and protective film.

The composition of Oculotect® fluid sine eye drops, containing the active compound polyvidone and also the electrolytes magnesium, potassium and sodium, is very similar to natural tears.

Pharmacokinetics:

Due to the size of the polyvidone molecule, penetration through the cornea is unlikely.

After oral administration, polyvidone with a molecular weight of 12,600 is rapidly excreted in the urine - the main part already after 11 hours.

After i.v. administration, long-term retention in the body can be avoided by reducing the part of polyvidone with a molecular weight higher than 250,000.

Indications:

Symptomatic treatment of dry eye conditions including Keratoconjunctivitis sicca (Substitute of tear fluid in case of unstable tear film or insufficient moistening of the eye surface). Lubrificant for hard and soft contact lenses.

Dosage and use:

4x1 drop daily or as required, depending upon the severity of the disease, to be instilled into the conjunctival sac. The volume in the single use container is sufficient for one application at the right and left eye.

NOTE: If Oculotect® fluid sine is used as a contact lens wetting agent, place one drop on the lens prior to insert it.

Discard Oculotect® fluid sine eye drops container immediately after use. Do not save unused contents.

Restrictions on use:

Contraindications: Patients with known hypersensitivity to one of the components of the eye drops.

Precautions: Patients who experience blurred vision after application of Oculotect® fluid sine eye drops should not drive or use machinery until their vision has cleared.

Pregnancy and lactation: There is no experience regarding the safety of Oculotect® fluid sine eye drops in human pregnancy or lactation. Administration during pregnancy and lactation is therefore not recommended, except for compelling reasons.

Adverse reactions:

Occasionally mild, transient burning or sticky sensation and very rarely irritation or hypersensitivity reactions.

Interactions:

In case of any additional local ocular treatment (e.g. glaucoma therapy) there should be an application interval of at least 5 minutes between the two medications. Oculotect® fluid sine eye drops always should be the last medication instilled.

Incompatibilities:

High salt concentrations, e.g. of sodium sulphate in cold and sodium chloride in warm conditions, can result in precipitation of povidone. Depending on the ionic strength of the solution methyl- and propyl-hydroxybenzoates easily form complexes with povidone.

Overdose: -**Additional information:**

Shelf-life: The single dose package remains sterile until the original closure is broken. Oculotect® fluid sine have to be used immediately after opening of the container. Discard the containers after use. Do not save unused contents. Oculotect® fluid sine can be used until the expiry date indicated with "EXP" on the pack.

Keep medicines out of the reach of children.

Presentation:

20 Single Dose Units containing 0.4ml each.

Date of last revision:

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Manufactured by

Lab. CIBA Vision FAURE

Annonay, France

For

NOVARTIS Ophthalmics AG

Hettingen, Switzerland