

POLY-TEARS® Lubricating Eye Drops

DESCRIPTION

Hypromellose 3 mg/mL, dextran 70 1 mg/mL, sodium borate, sodium chloride, potassium chloride, purified water and POLYQUAD® (polyquaternium-1) 0.011 mg/mL.

POLY-TEARS® Lubricating Eye Drops is sterile and has been specially formulated to provide soothing relief from the symptoms associated with dry, irritated eyes.

PHARMACOLOGY

The formula complements natural tears to lubricate and relieve irritation, grittiness and burning which may result from an inadequate natural tear film or exposure to wind or sun.

INDICATIONS

POLY-TEARS® Lubricating Eye Drops is a dry eye therapy for the temporary relief of burning, irritation and discomfort due to dryness of the eye. POLY-TEARS® Lubricating Eye Drops may be used for rewetting of all rigid gas permeable and soft (hydrophilic) contact lenses, including daily, extended wear, and disposable, to relieve discomfort and minor irritation or blurring which may be caused by wearing contact lenses.

CONTRAINDICATIONS

Hypersensitivity to any component of the product.

PRECAUTIONS

OPHTHALMIC USE ONLY

If patients experience headache, eye pain, vision changes, irritation of the eyes, persistent redness or if the condition worsens or persists for more than 72 hours, they are to remove any contact lenses, discontinue use of the eye drops and consult their doctor.

Effects on Fertility

There are no known effects of Poly-Tears® Lubricating eye drops on male or female fertility. Dextran 70 and hypromellose are pharmacologically inert compounds and would not be expected to have any effect on fertility.

Use in Pregnancy

No effects during pregnancy are anticipated, since the systemic exposure to dextran 70 and hypromellose following topical ocular administration is negligible. Additionally, dextran 70 and hypromellose are pharmacologically inert. Poly-Tears® Lubricating eye drops can be used during pregnancy.

Use in Lactation

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to dextran 70 and hypromellose is negligible. Additionally, both compounds are pharmacologically inert. Poly-Tears® Lubricating eye drops can be used during breast-feeding.

Interactions with other medicines

Although no interaction studies have been performed, clinically relevant interactions are not expected.

Effects on ability to drive and use machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

ADVERSE EFFECTS

The following adverse reactions have been reported during clinical studies with Poly-Tears[®] Lubrication eye drops and are classified according to the subsequent convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $<1/10$), uncommon ($\geq 1/1,000$ to $<1/100$), rare ($\geq 1/10,000$ to $<1/1,000$) and very rare ($<1/10,000$). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Eye disorders

Very common: vision blurred

Common: dry eye, eyelid disorder, abnormal sensation in eye, foreign body sensation in eyes, ocular discomfort

Uncommon: eye pruritus, eye irritation, ocular hyperaemia

Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.

Eye disorders: erythema of eyelid, eye pain, eye swelling, eye discharge, eyelid margin crusting, lacrimation increased

Immune system disorders: hypersensitivity

Nervous system disorders: headache

DOSAGE AND ADMINISTRATION

Instil 1 or 2 drops in the eye(s) as required or as directed by your doctor.

Do not touch dropper tip to any surface since this may contaminate solution.

OVERDOSAGE

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of accidental ingestion of the contents of one bottle.

PRESENTATION AND STORAGE CONDITIONS

POLY-TEARS is supplied in 15 mL DROP-TAINER[®] bottles.

Store below 25°C. Discard container 6 months after opening.

NAME AND ADDRESS OF THE SPONSOR

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