

SCHEDULING STATUS

Schedule 0

PROPRIETARY NAME AND DOSAGE FORM

REFRESH TEARS® Lubricating Eye Drops

COMPOSITION

REFRESH TEARS® Lubricating Eye Drops contain:

Carboxymethylcellulose sodium 5 mg/ml

Other ingredients: Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, boric acid and sodium borate decahydrate (as buffering agents) and purified water.

Stabilised oxychloro complex (Purite®) equivalent to 0,005 % m/v stabilised chlorine dioxide, a mild, non-sensitising preservative that, when used, ultimately changes into components of natural tears.

PHARMACOLOGICAL CLASSIFICATION

Conventional medicine: A 32.5 Artificial tear and contact lens solutions

PHARMACOLOGICAL ACTION

REFRESH TEARS® is a lubricating formulation similar to normal tears, containing a mild non-sensitising preservative that, when used, ultimately changes into components of natural tears.

Pharmacodynamic properties

The pharmacological effect of the active substance, carboxymethylcellulose sodium is not receptor-mediated, but is due to its property as viscosity enhancer resulting in increasing the retention time of REFRESH TEARS®.

Pharmacokinetic properties

Due to its high molecular weight carboxymethylcellulose sodium is unlikely to penetrate the cornea.

INDICATIONS

REFRESH TEARS® is used as a lubricant irritation and discomfort due to dryness of

the eye or due to exposure to wind or sun.

CONTRA INDICATIONS

Hypersensitivity to any of the ingredients.

REFRESH TEARS® should not be used in infants and small children under 3 years.

WARNINGS AND SPECIAL PRECAUTIONS

If eye pain, changes in vision, continued redness or irritation of the eye is experienced, or if the condition worsens or persists for more than 72 hours discontinue use and consult a medical doctor.

To avoid contamination, do not touch the tip of the container to any surface and avoid direct contact with the eye.

To avoid washout effects, concomitant ocular medication should be administered 15 minutes prior to the installation of REFRESH TEARS® (see “INTERACTIONS”).

Recap after use. Do not use if solution changes colour or becomes cloudy.

Effects on ability to drive and use machines

Should patients experience transient blurred vision, they should be advised not to drive or operate machinery until their vision has cleared.

INTERACTIONS

Concomitant ocular medication should be administered 15 minutes prior to the installation of REFRESH TEARS® (see “WARNINGS AND SPECIAL PRECAUTIONS”).

PREGNANCY AND LACTATION

Safe use during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Unless otherwise prescribed, instil 1 drop in the affected eye(s) 4 times a day or as needed.

SIDE EFFECTS

The following adverse drug reactions were reported with REFRESH TEARS®, the

most frequently reported treatment-related undesirable effect was burning (approximately 2 %):

Eye Disorders

Common ($\geq 1/100$, $< 1/10$): burning, dry eye, eye irritation/pruritus, eye discomfort, visual disturbance

Uncommon ($\geq 1/1000$, $< 1/100$): epiphora, conjunctival hyperaemia, eye pain, eye discharge.

The following additional adverse reactions have been identified during postmarketing use of REFRESH TEARS® in clinical practice. Because postmarketing reporting of these reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions.

Eye disorders: Foreign body sensation in eyes, ocular hyperaemia

Immune system disorders: Hypersensitivity including eye allergy with symptoms of eye swelling, eyelid oedema or erythema of eyelid

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No toxic side effects from systemic overdose are expected. Refer to “SIDE EFFECTS” and “WARNINGS AND SPECIAL PRECAUTIONS”. Treatment is symptomatic and supportive.

IDENTIFICATION

A clear, colourless to slightly straw-coloured solution, practically free from particulate matter.

PRESENTATION

REFRESH TEARS® is a sterile solution supplied in teal green opaque plastic dropper bottles with a cap, containing 15 ml of solution.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Do not refrigerate. To avoid contamination of the solution keep container tightly closed. Do not touch dropper tip to any surface. Do not use more than 30 days after first opening. Contents are sterile if seal is intact. KEEP OUT

OF REACH OF CHILDREN.

REGISTRATION NUMBER

37/32.5/0092

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

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