SCHEDULING STATUS
Schedule 0

PROPRIETARY NAME AND DOSAGE FORM
REFRESH LIQUIGEL® Lubricant Eye Drops

COMPOSITION
REFRESH LIQUIGEL® lubricant eye drops contain carboxymethylcellulose sodium 10 mg/ml.
Preservative: Purite® (stabilised oxychloro complex): 0,0075 % m/v

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

PHARMACOLOGICAL CLASSIFICATION
A.15.4 Ophthalmic preparations. Other.

PHARMACOLOGICAL ACTION
The mode of action of REFRESH LIQUIGEL® as a lubricant is entirely mechanical and has no pharmacological activity.

Due to its high molecular weight, REFRESH LIQUIGEL® is unlikely to penetrate the cornea.

INDICATIONS
REFRESH LIQUIGEL® is indicated for use as a lubricant in dry eye (keratoconjunctivitis sicca (KCS)).

This indication includes the temporary relief of burning, irritation, and/or discomfort due to dryness of the eye.

REFRESH LIQUIGEL® is indicated for lubricating and rewetting of soft and rigid gas permeable contact lenses. It is also indicated to relieve the dryness, irritation, and discomfort that may be associated with lens wear.

CONTRA-INDICATIONS

REFRESH LIQUIGEL® is contra-indicated in patients with previously demonstrated hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

For external use only. Do not use if solution changes colour or becomes cloudy.

Discontinue use and consult a medical practitioner 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.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Centre right away.

If irritation develops, discontinue lens wear and consult the eye practitioner.

Use before the expiration date marked on the container.

To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

To avoid washout effects, concomitant ocular medications should be administered at least 5 minutes apart from the instillation of REFRESH LIQUIGEL® (see 'INTERACTIONS').

To prevent infection, NEVER wet contact lenses with saliva or place lenses in mouth.

For use with rewetting indication:
Not for use in lens case.

Safety and effectiveness have not been demonstrated with REFRESH LIQUIGEL® in paediatric patients.

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 medications should be administered at least 5 minutes apart from the instillation of REFRESH LIQUIGEL® to avoid washout effects (see

"WARNINGS AND SPECIAL PRECAUTIONS").

PREGNANCY AND LACTATION

There are no data on the use of REFRESH LIQUIGEL® during pregnancy and lactation in humans. Animal studies did not show harmful effects with the active ingredient carboxymethylcellulose.

REFRESH LIQUIGEL® has not been studied in breast-feeding women; however, carboxymethylcellulose is not expected to be absorbed systemically; therefore there is no known potential for excretion in human breast milk.

DOSAGE AND DIRECTIONS FOR USE

REFRESH LIQUIGEL® may be used in conjunction with rigid gas-permeable and soft contact lenses.

Dry eye indication

Instil 1 or 2 drops in the affected eye(s) as needed.

Rewetting indication

To lubricate and rewet soft and rigid gas-permeable lenses during the day: With the lenses on the eye, apply 1 to 2 drops to each eye as needed, or as directed by the eye care practitioner. Blink several times.

SIDE EFFECTS

The following adverse drug reactions were reported with REFRESH LIQUIGEL®:

Eye disorders

Very common (≥1/10): Visual disturbances and eye discharge

Common (≥1/100, <1/10): Ocular discharge, eye pruritus, eye irritation, burning and discomfort, palpebral/conjunctival hyperaemia

Less frequent (≥1/1000, < 1/100): Eyelid oedema

The following additional adverse reactions have been identified during postmarketing use of REFRESH LIQUIGEL® 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: Eye pain, eyelid margin crusting and/or medication residue, foreign body sensation in eyes, ocular hyperaemia
Immune system disorders: Hypersensitivity including eye allergy

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
No toxic side effects from systemic overdose are expected. See "SIDE EFFECTS" and "WARNINGS AND SPECIAL PRECAUTIONS". Treatment is symptomatic and supportive.

IDENTIFICATION
Clear to slightly hazy, colourless to slightly yellow, viscous solution.

PRESENTATION
15 ml multiple dose, low-density polyethylene container and tip with a polystyrene cap.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Do not use more than 30 days after first opening. Do not touch tip of container to any surface. Replace cap after using. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
A38/15.4/0592

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