
SCHEDULING STATUS

Schedule 0

PROPRIETARY NAME AND DOSAGE FORM

CELLUFRESH® Eye Drops

COMPOSITION

CELLUFRESH® is an isotonic formulation and contains carboxymethylcellulose sodium 5 mg/ml, sodium chloride, sodium lactate, potassium chloride, calcium chloride dihydrate, magnesium chloride and purified water.

PHARMACOLOGICAL CLASSIFICATION

A. 15.4 Ophthalmic preparations. Other.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

CELLUFRESH® Eye Drops is an isotonic, lubricating, non-preserved formulation similar to normal tears.

INDICATIONS

CELLUFRESH® Eye Drops are indicated as a lubricant to relieve irritation and discomfort due to dryness of the eye or due to exposure to wind or sun.

CONTRA-INDICATIONS

Hypersensitivity to carboxymethylcellulose sodium or any other ingredient of CELLUFRESH®.

WARNINGS AND SPECIAL PRECAUTIONS

If irritation, pain, redness or changes in vision occur or if the patient's condition is worsened, treatment discontinuation should be considered and a new assessment made.

To avoid contamination or possible eye injury, do not touch tip of the vial to any surface and avoid contact with the eye.

Do not use if CELLUFRESH® packaging shows evidence of tampering. Do not use if solution changes colour or becomes cloudy.

Effects on ability to drive and use machines

Upon instillation, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.

INTERACTIONS

None known.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE

Ensure that the single-dose container is intact before use. Instil 1-2 drops in the affected eye/s 4 times a day as needed. The eye drop solution should be used immediately after opening. Discard any unused solution in opened container, i.e. do not re-use container for subsequent doses. The eye drops can be used with contact lenses.

If CELLUFRESH® is concomitantly used with other ocular eye medications there must be an interval of at least 15 minutes between the two medications (as displacement of a medication may occur).

SIDE EFFECTS

Eye disorders

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

The following other adverse reactions have reported since CELLUFRESH® has been marketed (frequency unknown):

Immune System Disorders

Hypersensitivity including eye allergy

Eye disorders

Eye pain, blurred vision, eye discharge, increased lacrimation, ocular hyperaemia

Injury, Poisons and Procedural Complications

Superficial injury of eye (from the vial tip touching the eye during administration) and/or

corneal abrasion.

To avoid contamination or possible eye injury, do not touch the tip of the vial to the eye or any other surface.

IDENTIFICATION

Clear, colourless to slightly yellow solution in low density polyethylene single-use containers.

PRESENTATION

Cardboard cartons containing 30 sterile single-use vials per carton. Each single-use container contains 0,4 ml CELLUFRESH®.

STORAGE INSTRUCTIONS

Store unopened container in a cool place (at or below 25 °C). Do not store opened single-use container. Discard any unused portion. **KEEP OUT OF REACH OF CHILDREN.**

REGISTRATION NUMBER

32/15.4/0477

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

Allergan Pharmaceuticals (Pty) Ltd
30 New Road (entrance off Bavaria Road)
Randjespark Ext 11, Midrand, 1682
Johannesburg, Gauteng
South Africa

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