SCHEDULING STATUS
Schedule 0

PROPRIETARY NAME AND DOSAGE FORM
CELLUVISC Eye Drops

COMPOSITION
CELLUVISC is an isotonic formulation and contains
Active ingredient:
Carboxymethylcellulose sodium 10 mg/ml
Excipients:
Calcium chloride dihydrate, potassium chloride, purified water, sodium chloride and sodium lactate

PHARMACOLOGICAL CLASSIFICATION
A 15.4 Ophthalmic preparations. Other.

PHARMACOLOGICAL ACTION
Carboxymethylcellulose is a lubricant.

INDICATIONS
CELLUVISC 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 or any of the ingredients, including excipients of CELLUVISC.

WARNINGS AND SPECIAL PRECAUTIONS
Discontinue use of CELLUVISC and consult a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens.

Contact lenses should be removed before each application and may be inserted after 15 minutes.

To avoid contamination or possible eye injury, do not touch the tip of the vial to any surface and avoid contact with the eye. Discard open single dose container after use.

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

Use before the expiration date marked on the container.

Effects on ability to drive and use machines
If blurred vision occurs, the patient should wait until the vision clears before driving or using machinery.

INTERACTIONS
Concomitant ocular medication should be administered 15 minutes prior to the instillation of CELLUVISC.

PREGNANCY AND LACTATION
Safety and efficacy during pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE
Instil one or two drops in the affected eye(s) as needed. Ensure that the single-dose container is intact before use. The eye drop solution should be used immediately after opening.

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

SIDE-EFFECTS
Eye disorders
Frequency not known: eye irritation, eye pain, blurred vision, increased lacrimation, ocular hyperaemia.

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

Eye disorders
Eye discharge, eye pain, eye pruritus, eyelid margin crusting and/or medication residue, foreign body sensation in eye, ocular hyperaemia, vision blurred and/or visual impairment.

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

Injury, poisons and procedural complications
Superficial injury of eye (from the vial tip touching the eye during administration) and/or corneal abrasion.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
None known.

IDENTIFICATION
A clear, colourless to very slightly yellow viscous solution in low density polyethylene single-use containers.

PRESENTATION
Cardboard cartons containing 30 single-use containers per carton. Each single-use container contains 0,4 ml CELLUVISC.

STORAGE INSTRUCTIONS
Store unopened container in a cool place (at or below 25 °C). Do not store opened single-use container.

The eye drop solution should be used immediately after opening. Any unused solution should be discarded. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
30/15.4/0144

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DATE OF PUBLICATION OF THE PACKAGE INSERT
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