PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM CELLUVISC, carboxymethylcellulose sodium 10 mg/ml, eye drops

Read all of this leaflet carefully because it contains important information for you

CELLUVISC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use CELLUVISC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CELLUVISC with any person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT CELLUVISC CONTAINS

- The active substance is carboxymethylcellulose sodium 10 mg/ml.
- The other ingredients are sodium chloride, sodium lactate, potassium chloride, calcium chloride dihydrate and purified water.

The ingredients in CELLUVISC were designed to match your natural tear composition.

2. WHAT CELLUVISC IS USED FOR

CELLUVISC is a tear substitute and contains the lubricant called carboxymethylcellulose sodium. It is used for the treatment of the symptoms of dry eye (such as irritation or dryness).

3. BEFORE YOU USE CELLUVISC

Do not use CELLUVISC

If you are hypersensitive (allergic) to carboxymethylcellulose sodium or any of the other ingredients of CELLUVISC (see section 1 for a full list of ingredients).

Take special care with CELLUVISC

- If you experience eye pain, changes in vision, continued redness, or irritation of the eye, or if your condition worsens, stop using the product. In these cases, consult your doctor.
- If you wear contact lenses, these should be removed before using CELLUVISC. The lenses can be put back again 15 minutes after you have applied your drops.
- To avoid contamination or possible eye injury, do not let the open-end of the single-dose container touch your eye or anything else.
- 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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using CELLUVISC.

Driving and using machinery

CELLUVISC may cause blurring of vision typically lasting 1 to 15 minutes. If you do experience temporary blurring, do not drive or use machines until your sight is clear.

Using other medicines with CELLUVISC

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are using other eye drops, leave at least 15 minutes before putting in CELLUVISC.

4. HOW TO USE CELLUVISC

Do not share medicines prescribed for you with any other person.

Always use CELLUVISC exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

CELLUVISC is for ocular use (applied on the eye).

The usual dose is one or two drops of CELLUVISC in the affected eye(s) as needed. Make sure that the single-dose container is intact before use. The eye drop solution should be used immediately after opening. To avoid contamination, do not let the open-end of the singledose container touch your eye or anything else. Wash your hands before use.



- 1. Tear one single-dose container from the strip.
- 2. Hold the single-dose container upright (with the cap uppermost) and twist off the cap.
- 3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release one drop into each eye. Blink your eyes a few times.

Do not re-use the single-dose container even if there is some solution left.

If irritation, pain, redness or changes in vision occur or if you feel your condition is getting worse, stop taking this medicine and consult your doctor or pharmacist.

If you have the impression that the effect of CELLUVISC is too strong or too weak, talk to your doctor or pharmacist.

If you use more CELLUVISC than you should

It will not cause you any harm. If you are worried, talk to your doctor or pharmacist. In the event of overdosage, consult your doctor or pharmacist. If neither is available contact at the nearest hospital or poison control centre.

If you forget to use CELLUVISC

Apply your next dose as required or at the normal time as directed by your pharmacist or doctor. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

CELLUVISC can have side effects.

The following side effects may be seen with CELLUVISC:

Frequency unknown: Allergic reactions (including eye allergy with eye swelling), eye irritation, eye pain, blurred vision, increase in tear production (also known as tearing), eye redness, eye itching, eye discharge, eyelid margin crusting and/or medication residue, foreign body sensation in the eye, eye injury to the surface of the eye due to the tip of the vial touching the eye during use.

Not all side effects reported for CELLUVISC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CELLUVISC, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF CELLUVISC

Store unopened container in a cool place (at or below 25 °C). Do not store opened single-use containers. The eye drop solution should be used immediately after opening. Any unused solution should be discarded. Do not use after the expiry date stated on the container.

Store all medicines out of reach of children. Return all unused medicines to your pharmacist. Do not disposed of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CELLUVISC

Cardboard cartons containing 30 single-use containers per carton. CELLUVISC is supplied in foil wrapped pouches. Each single-use container contains 0,4 ml CELLUVISC.

8. IDENTIFICATION OF CELLUVISC

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

9. REGISTRATION NUMBER

30/15.4/0144

10. NAME AND 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

11. DATE OF PUBLICATION

Date of registration: 28 June 1996 Date of most recent patient information leaflet as approved by Council: 29 July 2016