PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM CELLUFRESH[®] carboxymethylcellulose sodium 5 mg/ml, eye drops

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CELLUFRESH[®] with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen, or do not improve.

1. WHAT CELLUFRESH[®] CONTAINS

- The active substance is carboxymethylcellulose sodium 5 mg/ml
- The other ingredients are sodium chloride, sodium lactate, potassium chloride, calcium chloride dihydrate, magnesium chloride, and purified water.

2. WHAT CELLUFRESH[®] IS USED FOR

CELLUFRESH[®] is a tear substitute and contains a lubricant called carboxymethylcellulose sodium. It is used to relieve the symptoms of dry eye; such as burning, irritation, dryness, or eye pain.

3. BEFORE YOU USE CELLUFRESH[®]

Do not use CELLUFRESH[®]:

• If you are hypersensitive (allergic) to carboxymethylcellulose sodium or any of the other ingredients of CELLUFRESH[®].

Take special care with CELLUFRESH[®]:

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

Pregnancy and breastfeeding

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

Driving and using machinery

CELLUFRESH[®] may cause temporary blurred vision. Do not drive or use machinery until the symptoms have cleared.

Using other medicines with CELLUFRESH[®]

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

If you use CELLUFRESH[®] with another eye medicine, leave at least 15 minutes between putting CELLUFRESH[®] and the other medicine. Use any eye ointment or eye gel last.

4. HOW TO USE CELLUFRESH[®]

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

Always use CELLUFRESH[®] exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Ensure that the single-dose container is intact before use. The usual dose is 1 to 2 drops of CELLUFRESH[®] in each affected eye, 4 times a day, or as needed.

If you have the impression that the effect of CELLUFRESH[®] is too strong, or too weak, tell your doctor or pharmacist. You do not need to remove contact lenses before using CELLUFRESH[®]. Do not swallow.

To avoid contamination, do not let the bottle tip touch your eye or anything else. Always wash your hands before applying eye drops. Apply your eye drops in the following way:



- 1. Tilt your head back and look at the ceiling. Hold the container/vial tip lowermost over your eye.
- 2. Gently pull the lower eyelid down until there is a small pocket between the inside of the lower eyelid and the eyeball.
- 3. Squeeze the upturned container/vial to release a drop into your eye.

Do not re-use the opened container/vial for subsequent doses.

5. POSSIBLE SIDE EFFECTS

CELLUFRESH[®] can have side effects.

The following side effects may be seen with CELLUFRESH[®]:

Frequent: Eye irritation, (including burning and discomfort), eye pain, itchy eyes, visual disturbance

Frequency unknown: Allergic reactions (including eye allergy), eye pain, blurred vision, sticky eye, watery eye, redness of 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 CELLUFRESH[®] are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist, or other health care 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 CELLUFRESH[®]

- Store at or below 25 °C. Do not refrigerate.
- Keep the container in the outer carton.
- Store all medicines out of reach of children.
- Throw away any unused solution in the opened container/vial.
- Do not use after the expiry date stated on the container/vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CELLUFRESH[®]

CELLUFRESH[®] is available in cardboard cartons containing 30 sterile single-use vials per carton. Each single-use container contains 0,4 ml CELLUFRESH[®].

8. IDENTIFICATION OF CELLUFRESH®

CELLUFRESH[®] is a clear, colourless to slightly yellow solution.

9. REGISTRATION NUMBER / REFERENCE NUMBER

32/15.4/0477

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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

11. DATE OF PUBLICATION

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