Package leaflet: Information for the user CELLUVISC® 1% Eye Drops Solution

(carmellose sodium)

The name of your medicine is CELLUVISC 1% Eye Drops Solution but will be referred to as Celluvisc throughout the remainder of this

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. Always use this medicine exactly as described in this leaflet or as your pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- What Celluvisc is and what it is used for
- What you need to know before you use Celluvisc
- How to use Celluvisc
- Possible side effects How to store **Celluvisc**
- Contents of the pack and other information

1. What Celluvisc is and what it is used for

Celluvisc is a tear substitute and contains the lubricant called carmellose sodium. It is used for the treatment of the symptoms of dry eye (such as soreness, burning, irritation or dryness).

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Celluvisc

If you are allergic (hypersensitive) to carmellose sodium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If you wear contact lenses, these should be removed before using Célluvisc. The lenses can be put back again 15 minutes after you have applied your drops.

Other medicines and Celluvisc

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a

prescription.

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

Pregnancy and breast-feeding

Celluvisc can be used during pregnancy and breast-feeding.

Driving and using machines

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

3. How to use Celluvisc

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is 1-2 drops of Celluvisc in the affected eyes as

Make sure that the single-dose container is intact before use. The solution should be used immediately after opening.

To avoid contamination or possible eye injury, do not let the open-end of the single-dose container touch your eye or anything else. Wash your hands before use.







- Tear one single-dose container from the strip.
- Hold the single-dose container upright (with the cap uppermost) and twist off the cap.
- Gently pull down the lower eyelid to form a pocket. Turn the singledose 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. It is most important that you throw it away and do not keep it. 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 use more Celluvisc than you should

It will not cause you any harm. If you are worried, talk to your doctor or pharmacist.

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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following adverse reactions or medically relevant adverse events were reported during clinical trials:

Common side effects (occurring in between 1 and 10 patients in every

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

Post-Marketing Data

The following adverse reactions or medically relevant adverse events have been reported since the drug has been marketed:

Uncommon side effects (occurring in between 1 and 10 patients in every 1000) are:

Allergic reactions (including eye or eyelid swelling), blurring of vision, increase in tear production (also known as tearing), sticky eye, crusting of the eyelid and/or drug residue, a feeling that something is in your eye, redness of the eye/eyelid, eyesight worsening, eye injury to the surface of the eye due to the tip of the vial touching the eye during use.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Celluvisc

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use after the expiry/use before date on the vial tab/carton.
Do not use this medicine if you notice that the packaging is damaged.
Do not use if the solution has changed colour or has become cloudy.
Keep the single dose containers in the pouch and place the pouch back in the outer carton. Pouch is required to prevent moisture loss. If the product shows any signs of deterioration or discolouration consult

your pharmacist for advice. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Contents of the pack and other information What Celluvisc contains

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

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

Celluvisc 1% Eye Drops are available in pack sizes of 30 or 60 foilpouched single-dose containers.

Each foil pouch contains 10 single-dose containers.

The single-dose container has a twist-off cap. Each single-dose container contains 0.4 ml of solution.

Celluvisc 1% Eye Drops are manufactured by: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Ltd. Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

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Blind or partially sighted? Is this leaflet hard to see or read? Contact Quadrant Pharmaceuticals Ltd. Tel: 01204 471 269