

Package leaflet: Information for the user

Celluvisc® 1% w/v, Eye drops, solution, unit dose

carmellose sodium

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, or 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:

- 1 What **Celluvisc** is and what it is used for
- 2 What you need to know before you use **Celluvisc**
- 3 How to use **Celluvisc**
- 4 Possible side effects
- 5 How to store **Celluvisc**
- 6 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**Do not 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 **Celluvisc**. 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 in **Celluvisc**.

Pregnancy and breast-feeding

Celluvisc can be used during pregnancy and breast-feeding.

Driving and using machines

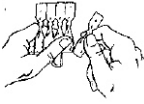


Celluvisc may cause short-lasting blurring of vision typically lasting 1 – 15 minutes. If you do experience temporary blurring, do not drive or use machines until your sight is clear.

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, or pharmacist or nurse has told you. Check with your doctor or, pharmacist or nurse if you are not sure.

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

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.

<p>1.</p> 	<p>Tear one single-dose container from the strip.</p>
<p>2.</p> 	<p>Hold the single-dose container upright (with the cap uppermost) and twist off the cap.</p>
<p>3.</p> 	<p>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.</p>

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 100) are:

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 HPRA Pharmacovigilance, Website: www.hpra.ie. 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 use Celluvisc after the expiry date which is stated on the single-dose container tab and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original pack to protect from light.

Do not use if the package shows signs of tampering. Do not use if solution changes colour or becomes cloudy.

Ensure that the single dose container is intact before use. Discard any unused solutions (i.e. once opened do not re-use container for subsequent doses).

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.

6 Contents of the pack and other information

What Celluvisc contains

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

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

What Celluvisc looks like and contents of the pack

Celluvisc is an eye drop solution. It is presented as a clear, colourless to pale yellow solution in a small see-through (bubble-like) casing (known as a 'single-dose container'). The single-dose container has a twist-off cap. Each single-dose container contains 0.4 ml of solution.

Each pack contains 30 single-dose containers.

Parallel Product Authorisation Holder:

Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by:

Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland.

The manufacturer is:

Allergan Pharmaceuticals Ireland
Castlebar Road, Westport, Co. Mayo, Ireland.

Celluvisc is a registered trademark of Allergan Inc.

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**Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon Pharmaceuticals
(Ireland) Limited,
Tel:+35318710550 for help.**

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Celluvisc
Finland	Celluvisc 1.0% Silmätipat, liuos
Germany	Celluvisc 1% Augentropfen
Greece	Celluvisc 1.0% w/v Οφθαλμικές σταγόνες, διάλυμα
Ireland	Celluvisc 1.0% w/v Eye drops, solution, unit dose
Portugal	Celluvisc, colírio, solução a 1,0%.
Spain	Viscofresh 10 mg/ml Colirio en solución
UK	Celluvisc 1.0% w/v Eye drops, solution, unit dose