

Package leaflet: Information for the user
Celluvisc® 1.0 % 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 from pharmacies. 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:

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 substitute for tears 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) caused by not producing enough tears to keep the eye wet.

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

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 between putting in the other eye drops and 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 in 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 eye/eyes as needed.

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

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. It is most important that you throw it away and do not keep it.

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 (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 100 people)

- 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

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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the single-dose container tab, the foil pouch and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the single dose containers in the pouch and place the pouch back in the outer carton. Pouch is required to prevent moisture loss.

Do not use if the packaging shows evidence of tampering.

Do not use if solution changes colour or becomes cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. 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 dihydrate and purified water.

The ingredients used in Celluvisc were chosen to match what appears in tears produced naturally by the eye

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 10, 20, 30, 40, 60 or 90 foil-pouched single-dose containers.

Each foil pouch contains 10 single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

AbbVie Limited
Citywest Business Campus
Dublin 24
Ireland

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the website of www.hpra.ie

To listen to or request a copy of this leaflet in Braille, large print or audio please contact the local representative of the Marketing Authorisation Holder.