

Package leaflet: Information for the user

CELLUVISC® 0.5% 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 you 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 hypersensitive (allergic) to carmellose sodium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- 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.

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 drops and CELLUVISC®.

Pregnancy and breast-feeding

You can use CELLUVISC[®] if you are pregnant and when you are breast-feeding.

Driving and using machines

CELLUVISC[®] may cause temporary blurring of vision. If you do experience temporary blurring, do not drive or use machines until your sight is clear.

Read all the information in this leaflet before using CELLUVISC[®].

If you are unsure about anything, discuss it with your doctor, nurse or pharmacist.

3. How to use CELLUVISC[®]

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/each affected eye, 4 times a day or as often as needed.

You do not need to remove contact lenses before using CELLUVISC[®].

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.



1. Tear one single-dose container from the strip.
2. Hold the single-dose container upright (with the top uppermost) and twist off the top.
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®

Use a single drop in each eye that needs treatment as soon as you remember, and then go back to your regular routine. Do not use a large number of drops to make up for forgetting to put drops in your eye or eyes earlier.

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 side effects are classified into the following categories, depending on how often they occur:

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1,000 people
Very rare	may affect up to 1 in 10,000 people
Not known	frequency cannot be estimated from the available data

The following side effects may be seen with CELLUVISC® :

Common	Eye irritation (including burning and discomfort), eye pain, itchy eyes, visual disturbance.
Not known	Allergic reactions (including eye allergy), 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.

Reporting of side effects

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. You can also report side effects directly via:

UK

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

IMB Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.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 store above 25°C.

Do not use this medicine after the expiry date (use by 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 use if CELLUVISC® packaging shows evidence of tampering. Do not use if solution changes colour or becomes cloudy. Used CELLUVISC® eye drop containers can be disposed of as household waste. Any unused containers can be returned to the pharmacist or he can tell you how to dispose of them safely (in order to protect the environment).

6. Contents of the pack and other information

What CELLUVISC® contains

- The active ingredient is carmellose sodium 5 mg/ml.
- The other ingredients are sodium chloride, sodium lactate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and purified water. Small amounts of sodium hydroxide or hydrochloric acid may be added to bring the solution to the correct pH (a measure of the acidity or alkalinity of the solution).

The ingredients and the amount 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 a clear, colourless to pale yellow eye drops solution in a small see-through (bubble-like) casing (known as a 'single-dose container'). The single-dose container has a twist-off top. Each single-dose container contains 0.4 ml of eye drops solution.

Each pack contains 5, 30 or 90 single-dose containers. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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