

Artelac®

Preservative Free Single Dose Unit

3.2 mg/ml eye drops, solution

hypromellose

The name of your medicine is Artelac Preservative Free Single Dose Unit and it is called Artelac Preservative Free in this leaflet.

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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. 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 Artelac Preservative Free is and what it is used for
2. What you need to know before you use Artelac Preservative Free
3. How to use Artelac Preservative Free
4. Possible side effects
5. How to store Artelac Preservative Free
6. Contents of the pack and other information

1. What Artelac Preservative Free is and what it is used for

Artelac contains the active ingredient hypromellose which acts as a lubricant to treat symptoms of dry eye. It is a soothing solution that is used as an artificial tear when the eyes are lacking in tears.

Your eyes will normally produce just enough natural tears to allow them to move easily and comfortably. If your eyes do not produce enough tears they can become dry, red and painful. Your drops keep the surface of the eye lubricated (moist) when production of tears is less than normal, and has a refreshing, cooling action. The hypromellose in these drops increases the thickness of the solution which has a moisturising effect and helps the solution to stay in contact with your eye for a longer period of time.

Artelac Preservative Free can be used by children, adults and the elderly.

2. What you need to know before you use Artelac Preservative Free

Do NOT use Artelac Preservative Free

- If you are allergic to hypromellose or any of the ingredients of this medicine (listed in Section 6).

Warnings and precautions

- Talk to your doctor or pharmacist before using Artelac Preservative Free
- If your eyes continue to feel dry and sore, stop using your drops and tell your doctor.

Other medicines and Artelac

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

- All eye drops can cause a short term blurring of vision when first used, so you should wait until your eyes are clear before driving or using machines.

Artelac Preservative Free contains disodium phosphate dodecahydrate and sodium dihydrogen phosphate dihydrate

This medicine contains phosphates. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Artelac Preservative Free

Always use your solution exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

This medicine is only to be used as drops applied into one or both eye(s).

Ensure the dropper tip does not touch any surface including the eye surface.

The recommended dose is

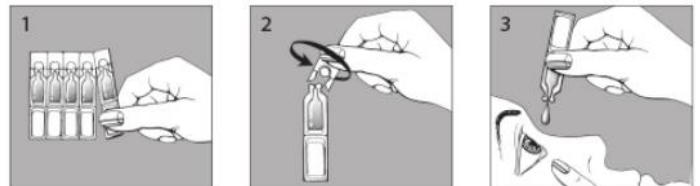
The usual dose is to apply 1 drop in the corner of the eye, nearest the nose, 3 to 5 times each day or as required to give enough lubrication.

Dry eye is a condition that varies from person to person. Use the drops as often as you think necessary.

Directions for use

Wash your hands before using your drops

- Sit down in front of a mirror so that you can see what you are doing
- Wipe your eyes to clear any residual wateriness or discharge
- Holding the unit by the label end, remove a single-dose unit from the pack (see picture 1)
- Twist the cap off the single-dose unit (see picture 2)
- Pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid, in the corner nearest the nose (see picture 3)
- Release the lower eyelid, and blink a few times to make sure the eye is covered by the liquid
- Repeat the procedure for your other eye
- This product is for single use only - when you have finished, throw away the single-dose unit (see Section 5)



If you use more Artelac Preservative Free than you should

If you accidentally use a larger dose than recommended, this may cause some blurring of vision, which will soon pass.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take Artelac Preservative Free

Do not take a double dose to make up for a forgotten dose.

4. Possible Side Effects

Like all medicines, Artelac Preservative Free can cause side effects, although not everybody gets them.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

You may briefly have blurred vision or a slight stinging feeling after using your drops (frequency cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Artelac Preservative Free

- **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 carton and single dose unit after 'EXP'.**
 - **The expiry date refers to the last day of that month.**
 - **If the expiry date has passed, take the medicine back to your pharmacist.**
- Do not store your drops above 25°C.
- Keep the single-dose units in the outer box.
- Your eye drops are sterile until first opened. It is important to keep the drops as clean as possible during use.
- Your drops come in single-dose, single-use units, which should be thrown away immediately after use.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Artelac Preservative Free contains:

- The active ingredient is: hypromellose 3.2 mg/ml (0.32 % w/v).
- The other ingredients are: disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, sorbitol (E 420) and water for injections.

What Artelac Preservative Free looks like and contents of the pack

These eye drops are a sterile clear solution and are supplied in plastic single-dose units. Each single dose unit has a volume of 0.5 ml. Your drops contain no preservative and therefore each unit is for single-use only. Each pack contains 30 and 60 single-dose units.

Your drops do not contain a preservative and can be used if your eyes are sensitive to preservatives or if you wear contact lenses.

Manufacturer

Dr. Gerhard Mann Chem-Pharm-Fabrik GmbH, Brunsbutteler Damm 165/173, 13581 Berlin, Germany or Laboratoire UNITHER, ZI de la Guérie, 50211 Coutances Cedex, France or Laboratoire UNITHER, 1 Rue de L'Arquerie, 50200 Coutances, France.

The product is procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA0465/454/001

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This leaflet was last revised in November 2023