

Package leaflet: Information for the user

Artelac 3.2 mg/mL eye drops, solution hypromellose

Read all of this leaflet carefully before you start using 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 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Artelac is and what it is used for
2. What you need to know before you use Artelac
3. How to use Artelac
4. Possible side effects
5. How to store Artelac
6. Contents of the pack and other information

1. What Artelac is and what it is used for

Moisturizing Artelac eye drops are used to alleviate symptoms caused by the drying of eye surface. The drying of eye surface may be caused by changes in the tear layer, low production of tears or incomplete closing of the eyelids.

Moisturizing Artelac eye drops increase the amount of liquid on the eye's surface and lubricate the eye and the eyelid.

2. What you need to know before you use Artelac

Do not use Artelac eye drops:

- if you are allergic (hypersensitive) to hypromellose or any of the other ingredients of Artelac.

Other medicines and Artelac

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you use different ophthalmic medicines, you should pause for 5 minutes between using different eye drops and use Artelac last.

If you wear contact lenses, remove them before applying the medicine; they can be put back in after 15 minutes.

Pregnancy, breast-feeding and fertility

The use of Artelac during pregnancy has not been studied.

Talk to your doctor or pharmacist before using this medicine.

Driving and using machines

If the eye drops cause blurred vision, wait until visual acuity has recovered.

Artelac contains phosphate buffers

This medicine contains 0.051 mg of phosphates per drop of solution, equivalent to 1.84 mg/ml. If you have severe damage to the front of the eye (the cornea), phosphates can very rarely cause cloudy foci on the cornea due to calcium deposits during treatment.

3. How to use Artelac

The usual dose is 1 drop 3-5 times a day.

- wash your hands
- find the most comfortable position to administer the eye drops (you should sit, lie down or stand in front of a mirror)

Application

1. Open the bottle. Do not touch anything with the bottle's tip to avoid contamination.
2. Tilt your head back and hold the bottle above the eye.



3. Pull the lower lid down and look up. Apply 1 drop into the eye 3-5 times a day by pressing the bottle lightly from the sides.



4. Blink a couple of times for the drop to become distributed over the eye. Close the bottle.



If you feel that the effect of Artelac is too strong or too weak, talk to your doctor or pharmacist.

4. Possible side effects

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

Artelac eye drops may cause temporary blurring of vision or eye tingling, pain, redness, itching, increased tear flow, the feeling of a foreign body in the eye or sticky eyelids.

In some patients with significant corneal damage the use of phosphate-containing eye drops has very rarely caused corneal calcification.

Hypersensitivity reaction

Although it is very rare, it is still possible that the medicine will cause hypersensitivity even in the case of a single use. If there is a suspicion of hypersensitivity (severe itching, redness and swelling of eyelids), stop using Artelac eye drops and contact a doctor immediately.

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 www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Artelac

- Keep this medicine out of the sight and reach of children.
- Keep the bottle tightly closed.
- Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

An open bottle of eye drops may be used for 28 days.

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 contains

- The active substance is hypromellose. 1 mL of the solution contains 3.2 mg of hypromellose.
- The other ingredients are cetrимide, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, disodium edetate, sorbitol and water for injection.

What Artelac looks like and contents of the pack

10 mL of solution in a transparent, low-density polyethylene (LDPE) plastic bottle with a LDPE dropper and a high-density polyethylene (HDPE) screw cap.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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