

Artelac® 0.32% w/v eye drops, Single Dose Unit, Preservative Free (hypromellose)

Your medicine is known by the above name, but will be referred to as Artelac® SDU Preservative Free throughout this leaflet.

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

Always take 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 after number of days.

What is in this leaflet:

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

1. WHAT ARTELAC® SDU PRESERVATIVE FREE IS AND WHAT IT IS USED FOR

Artelac® SDU Preservative Free contains hypromellose as the active ingredient, which is a form of cellulose.

Your drops are used as a tear substitute and lubricant when applied to the eye.

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 the eye for a longer period of time.

These drops work by soothing the eye and giving tear-like lubrication to the eyes and eye lids.

They are used to treat the symptoms of "dry eye", which is a dehydration of the surface of the eye because no natural tears are being produced. Dry eye can also be caused if it is not possible to close your eyelids partly or completely.

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 TAKE ARTELAC® SDU PRESERVATIVE FREE

Do not use Artelac® SDU 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 taking Artelac® SDU Preservative Free
- if you wear soft contact lenses – take out your lenses before using Artelac® SDU Preservative Free and then wait for at least 15 minutes after using these drops before putting your lenses back in.

Other medicines and Artelac® SDU Preservative Free

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- You should wait 5 minutes before using any other eye medication.

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.

Important information about some of the ingredients in this medicine:

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

This medicine contains 0.068mg phosphates in each drop which is equivalent to 1.84mg/ml. 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 TAKE ARTELAC® SDU PRESERVATIVE FREE

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

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

The recommended dose is

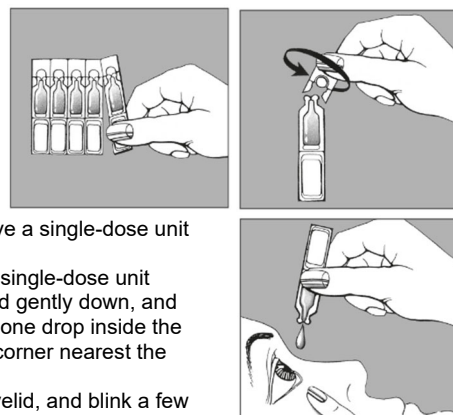
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is to apply one 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

- 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
- twist the cap off the single-dose unit
- pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid, in the corner nearest the nose
- 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
- when you have finished, throw away the single-dose unit



Always read the label before using this medicine.

If you use more Artelac® SDU 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.

Make sure you know how and when to use your medicine. If you are not sure about using your drops, ask your pharmacist.

If you forget to take Artelac® SDU Preservative Free

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Artelac® SDU Preservative Free can cause some side effects, although not everybody gets them. If you experience any difficulty stop using your drops and talk to your doctor or pharmacist.

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.

Like all eye drops you may briefly have blurred vision or a slight stinging feeling after using your drops.

There is also a slight possibility that irritation or itching of the eye may occur in a very small number of people. (frequency cannot be estimated from the available data)

If any side effect 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ARTELAC® SDU PRESERVATIVE FREE

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- 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.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Artelac® SDU Preservative Free contains

Each solution contains Hypromellose 0.32% w/v.

Also contains sorbitol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate and purified water for injections.

What Artelac® SDU Preservative Free looks like and contents of the pack

Artelac® SDU Preservative Free are a sterile clear solution and are Supplied in plastic single dose units has a volume of 0.5ml. Your drops contain no preservative, therefore each unit is for single-use only.

Artelac® do not contain preservative and can be used by patients who are hypersensitive to preservatives or who wear contact lenses.

Each pack contains 30 or 60 single dose units.

This medicine is for you, never give it to anyone else, even if they appear to have the same symptoms as you.

Return any unused medicine to your pharmacist.

Manufactured by Dr Gerhard Mann Chem. Pharm. Fabrik GmbH, Brunsbütteler Damm 165-173, 13581 Berlin, Germany.

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Is this leaflet hard to see or read?

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Tel: 020 8896 9054 for help.

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