

## PACKAGE LEAFLET: INFORMATION FOR USER

**ARTELAC® 0.32 % w/v EYE DROPS SINGLE DOSE UNIT  
(hypromellose)**

Your medicine is known as Artelac 0.32 % w/v Eye Drops Single Dose Unit but will be referred to as Artelac throughout the following 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 pharmacists 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 is and what it is used for
2. What you need to know before you take Artelac
3. How to take 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**

Artelac 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****Do not use Artelac**

- 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
- if you wear soft contact lenses – take out your lenses before using Artelac and then wait for at least 15 minutes after using these drops before putting your lenses back in.

**Other medicines and Artelac**

- 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 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**

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**

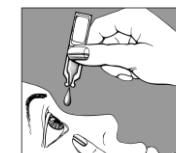
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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 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**

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Artelac 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 or pharmacist. 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](http://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

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 25°C.
- 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.
- Do not use after the expiry date printed on the pack.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of 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 dispose of medicines no longer required. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Artelac contains

- Solution contains hypromellose 0.32% w/v.
- Artelac also contains sorbitol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate and water for injections

### What Artelac looks like and contents of the pack

Artelac is a clear, sterile eye drops solution in a single dose unit. Artelac is available in pack sizes of 30 and 60 single dose units.

### Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd., Chemilines House, Alperton Lane, Wembley, HA0 1DX.

### Manufacturer

This product is manufactured by

- DR GERHARD MANN CHEM. PHARM., FABRIK GMBH, BRUNSBÜTTELER, DAMM 165/173, 13581 BERLIN – GERMANY.
- LABORATOIRE UNITHER, ZI DE LA GUÉRIE, 50211 COUTANCES – FRANCE.



PL 19488/1698

Leaflet revision date: 04 May 2022

**Blind or partially sighted? Is this leaflet hard to see or read? Call 02087997607 to obtain the leaflet in large print, tape, CD or Braille.**

*Artelac® is a registered trade mark of Dr. Gerhard Mann Chem-pharm. Fabrik GmbH, Germany.*