

# Artelac® Preservative Free Single Dose Unit (hypromellose)

## PATIENT INFORMATION LEAFLET

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

**Please read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However you still need to use Artelac Preservative Free carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

### 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

Your drops contain 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 these drops

- If you have been told, or know, that you are allergic (hypersensitive) to any of the ingredients (see Section 6).

#### Take special care with these drops

- If your eyes continue to feel dry and sore, stop using your drops and tell your doctor.

#### Taking other medicines

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

#### Pregnancy and breast-feeding

- This solution can be used if you are pregnant or breast-feeding.

### 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.

### 3. HOW TO USE ARTELAC PRESERVATIVE FREE

Always use your solution exactly as your doctor or pharmacist has told you to. You should 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.

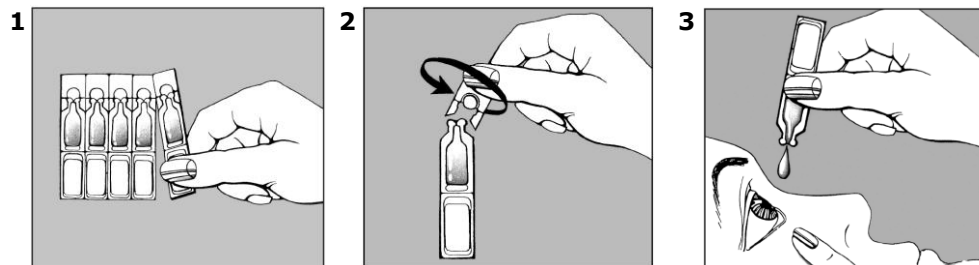
#### Dosage

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.

### 4. POSSIBLE SIDE EFFECTS

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

You may briefly have blurred vision or a slight stinging feeling after using your drops.

#### 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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.imb.ie](http://www.imb.ie); E-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.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 out of the sight and reach of children.**
- **Do not use this medicine after its expiry date.**
  - **Check the expiry date (Exp) on the label before you begin to use your medicine.**
  - **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 above 25°C. Keep container in the outer carton.
- 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 your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- 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 Preservative Free contains

Each ml of solution contains 3.2mg hypromellose (0.32% w/v).

Also contains: disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, sorbitol (E420) and water for injections.

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

Artelac Preservative Free is a sterile solution for eye drops, presented in plastic single dose, single use units.

Each single dose unit has a volume of 0.5ml.

Artelac Preservative Free is available in packs containing 60 x 0.5ml single dose units.

Your drops contain no preservative and therefore each unit is for single use only.

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

Manufactured by: Laboratoire CHAUVIN, Z. I. Ripotier Haut, 07200 AUBENAS, France.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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