

BAUSCH + LOMB

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DESCRIPTION: Artelac Eye Drops Insert - Ireland

PART No.: 9192101.40728PB188/6-IE/UK SPEC No.: 5234

PLACED IMAGES: GEC0142 Augen_Tropfflasche.tif

COATING PER SPECIFICATION

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DIELINE DOES NOT PRINT

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Artelac[®] 3.2 mg/ml Eye Drops, Solution Hypromellose

The name of your medicine is Artelac 3.2 mg/ml Eye Drops, Solution and it is called Artelac 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 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 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

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 can be used by children, adults and the elderly.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ARTELAC

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 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.
- 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

- These drops 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

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).

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

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



221



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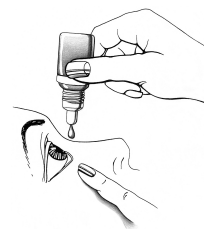
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Directions for use

- 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
- Unscrew the cap from the bottle and check the dropper is clean
- Pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid, in the corner nearest the nose (see picture)
- Take care not to touch the dropper with your eye or fingers
- 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, put the cap back on the bottle tightly



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.

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 can cause side effects, although not everybody gets them.

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ARTELAC

- Keep out of the reach and sight of children.
- **Do not use this medicine after its expiry date.**
 - Check the expiry date 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 your drops above 25°C.
- Your eye drops are sterile until first opened. It is important to keep the drops as clean as possible during use. Do not touch the dropper tip on the eye or any other surface.
- Your drops come in bottle which should be thrown away 28 days after first opening.
- Unused 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

- The active ingredient is: hypromellose 3.2 mg/ml (0.32 % w/v).
- The other ingredients are: cetrimide, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, disodium edetate, sorbitol and water for injections. The preservative in your eye drops is cetrimide, which means that Artelac can be used if your eyes are sensitive to other preservatives such as benzalkonium chloride.

What Artelac looks like and contents of the pack

These eye drops are a clear sterile solution and are supplied in plastic eye drop bottles. Each bottle has a volume of 10 ml.

Marketing Authorisation Holder

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Manufacturer

Dr Gerhard Mann Chem-pharm Fabrik GmbH, 13581 Berlin, Germany

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