

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vidisic[®] *Preservative Free Single Dose Unit*

Carbomer

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

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

This medicine is available without prescription. However you still need to use Vidisic 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.
- 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.

What is in this leaflet:

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

1. WHAT VIDISIC PRESERVATIVE FREE IS AND WHAT IT IS USED FOR

Your gel contains the active ingredient carbomer, which acts as a lubricant to treat symptoms of dry eye. It is a soothing gel 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 gel keeps the surface of the eye lubricated when production of tears is less than normal, and has a refreshing, cooling action. The carbomer in this gel holds moisture and releases this onto the surface of the eye to help relieve the feeling of dryness.

This gel can be used by children, adults and the elderly.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VIDISIC PRESERVATIVE FREE

Do NOT use Vidisic Preservative Free

- If you are allergic to Carbomer or any of the ingredients of this medicine (listed in Section 6).
- If you think you have conjunctivitis (an eye infection) which can also cause the eye to be red and inflamed.

Warnings and precautions

Talk to your doctor or pharmacist before using Vidisic Preservative Free

- If you wear contact lenses – take out your lenses before using Vidisic Preservative Free and then wait for at least 15 minutes after using this gel before putting your lenses back in.

Children and adolescents aged to 18 years:

The safety and efficacy of Vidisic Preservative Free in children and adolescents at the dosage recommended in adults has been established by clinical experience, but no clinical trial data are available.

Other medicines and Vidisic Preservative Free

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are using any other eye medicines, use Vidisic Preservative Free last, at least 15 minutes after any other eye drop or gel.

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 using Vidisic Preservative Free. They will decide if Vidisic Preservative Free is suitable for you to use.

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 VIDISIC PRESERVATIVE FREE

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

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

The recommended dose is

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.

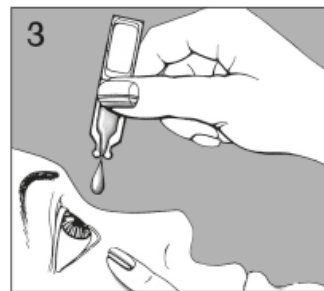
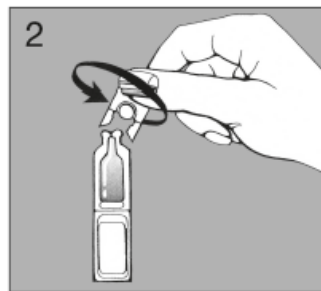
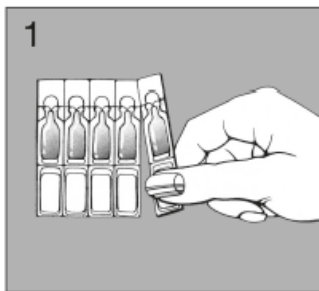
Dry eye is a condition that varies from person to person. Use the gel as often as you think necessary.

Use in children and adolescents aged to 18 years:

The safety and efficacy of Vidisic Preservative Free in children and adolescents at the recommended dose in adults has been established by clinical experience, but no clinical trial data are available.

Directions for use

- Wash your hands before using your gel
- 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 (see picture 3)
- 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 gel
- 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 Vidisic 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.

If you forget to take Vidisic Preservative Free

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

4. POSSIBLE SIDE EFFECTS

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

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.

Side effects such as a feeling of burning, irritation, stinging, swelling, redness and inflammation of the eye have been reported in a small number of people, frequency cannot be estimated from the available data.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. HOW TO STORE VIDISIC PRESERVATIVE FREE

- Keep this medicine out of sight and reach 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 eye gel above 25°C.
- Keep the single-dose units in the outer box.
- 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-use, single-dose units, which should be thrown away immediately after use.
- Do not throw away any medicines 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 Vidisic Preservative Free contains

- The active ingredient is: carbomer 0.2% w/w (2mg/ml).
- The other ingredients are: sorbitol, disodium phosphate dodecahydrate, sodium hydroxide and water for injections.

What Vidisic Preservative Free looks like and contents of the pack

This eye gel is a clear sterile gel and is supplied in plastic single-dose units. Each single dose unit has a volume of 0.6 ml. Your gel contains no preservative and therefore each unit is for single-use only. Each pack contains 20, 30, 60 or 120 single-dose units. Not all pack sizes may be marketed.

Your gel does not contain a preservative and can be used if your eyes are sensitive to preservatives or if you wear contact lenses.

Marketing Authorisation Holder

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