

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vidisic® 0.2% w/w Eye Gel

Carbomer

The name of your medicine is Vidisic 0.2 % w/w Eye Gel and it is called Vidisic 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 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

In this leaflet:

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

1. WHAT VIDISIC 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.

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 USE VIDISIC

Do not use Vidisic:

- 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.
- If you wear soft contact lenses – take out your lenses before using Vidisic and then wait for at least 15 minutes after using this gel before putting your lenses back in.
- If you experience burning, stinging, swelling, irritation of the eyes, or any new or troubling eye symptoms, discontinue use and consult your doctor.

Children and adolescents aged to 18 years:

The safety and efficacy of Vidisic 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

- 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 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. They will decide if Vidisic 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.

Vidisic contains cetrimide

Your gel contains cetrimide which is used as a preservative.

When used over a long period of time, cetrimide may cause eye irritation such as redness, burning or a feeling that there is something in your eye.

3. HOW TO USE VIDISIC

Always use your eye gel exactly as your doctor or pharmacist has told you to. You should 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).

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 gel as often as you think necessary.

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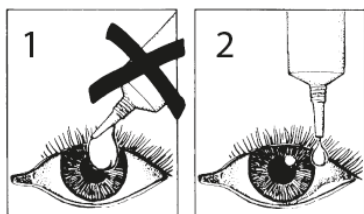
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Directions for use

- 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
- Unscrew the cap from the tube and check the nozzle is clean
- Hold the tube in an upright position with the nozzle pointing down.

This allows a small drop to form, which falls easily from the tip of the nozzle (see pictures 1 – 2)

- Pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid (see picture 2)
- Take care not to touch the nozzle tip 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
- When you have finished, put the cap back on the tube



If you use more Vidisic 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 forget to use your medicine, do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 (see also section 2 „Warning and precautions”).

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:

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafety@hpra.ie.

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

5. HOW TO STORE VIDISIC

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not store your eye gel above 30°C.
- Your eye gel is sterile until first opened. It is important to keep the gel as clean as possible during use. Do not touch the nozzle tip on the eye or any other surface.
- Your gel comes in a tube which should be thrown away 1 month after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Vidisic contains

- The active ingredient is: carbomer 0.2% w/w. Each 1g of gel contains 2mg of carbomer.
- The other ingredients are: cetrimide, sorbitol, sodium hydroxide and water for injections.

What Vidisic looks like and contents of the pack

This eye gel is a clear sterile gel and is supplied in a plastic/aluminium tube. Each tube contains 10g of gel.

Marketing Authorisation Holder

Bausch Health Ireland Ltd.,

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Manufacturer

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