

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vidiscic[®] 0.2% w/w Eye Gel Carbomer

The name of your medicine is Vidiscic 0.2 % w/w Eye Gel and it is called Vidiscic 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 Vidiscic 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 Vidiscic is and what it is used for
2. What you need to know before you use Vidiscic
3. How to use Vidiscic
4. Possible side effects
5. How to store Vidiscic
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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VIDISIC

Do NOT use this gel

- If you have been told, or know, that you are allergic (hypersensitive) to any of the ingredients (see Section 6 and end of Section 2).
- If you think you have conjunctivitis (an eye infection) which can also cause the eye to be red and inflamed.

Take special care with this gel

- If you wear soft contact lenses – take out your lenses before using Vidiscic 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 Vidiscic in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

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.
- If you are using any other eye medicines, use Vidisic last, at least 15 minutes after any other eye drop or gel.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding ask your doctor or pharmacist 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.

Important information about some of the ingredients

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.

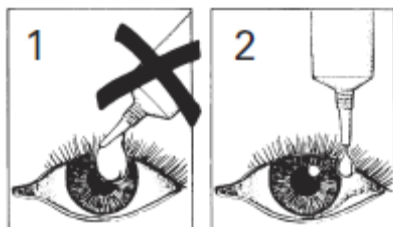
Dry eye is a condition that varies from person to person. Use the gel as often as you think necessary.

Children and adolescents aged to 18 years:

The safety and efficacy of Vidisic in children and adolescents at the posology recommended 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
- 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vidisic 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.

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 VIDISIC

- **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 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.
- 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 Vidisic contains

- The active ingredient is: carbomer 0.2% w/w. Each 1g of gel contains 2mg of carbomer.
- The other ingredients are: cetrimide (see end of Section 2 for further information), 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

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Manufacturer

Dr. Gerhard Mann, 13581 Berlin, Germany.

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This leaflet was approved