

Package leaflet: Information for the user

Gel Tears[®]

(carbomer)

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

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

1. What Gel Tears is and what it is used for

Gel Tears is a clear colourless liquid gel and contains a lubricant that is used as a substitute for natural 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 and irritated. It can also be used in patients who suffer from sore eyes because their tear film is unstable. Gel Tears will help keep your eyes comfortable.

2. What you need to know before you use Gel Tears

Do not use Gel Tears if you are allergic to any of the ingredients of this medicine (listed in section 6).

Other medicines and Gel Tears

If Gel Tears is used at the same time with other eye drops/eye ointments, there should be an application time interval of approximately 15 minutes between use of such other medications and Gel Tears should always be the last medication to be applied.

Tell your doctor or pharmacist if you are taking, have recently or might take any other medicines.

Warnings and Precautions

Your vision may become blurred if too much gel is added at one time, or if you use your medicine more often than is required. This effect can last for up to an hour. If you are affected you may be able to speed up recovery of normal vision by blinking vigorously for a few seconds. If this does not work, try gently rubbing the eyelid.

This should help the gel to collect in the conjunctival sac beneath the eye where it will no longer interfere with your vision.

Children and adolescents aged to 18 years:

The safety and efficacy of Gel Tears in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

Pregnancy, breast-feeding and fertility

Do not use Gel Tears if you are pregnant, may be pregnant, or are breast-feeding. Ask your doctor or pharmacist for advice.

Contact lenses

Take special care with Gel Tears if you wear contact lenses. Contact lenses should be removed during treatment with Gel Tears. And then wait for 15 minutes after application before putting them back in.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Driving and using machines

As with all eye preparations, you may have blurred vision for a little while after putting the gel in. Wait until your vision is clear before driving or using machines.

3. How to use Gel Tears

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. You should take care not to touch the end of the dropper nozzle onto your eyes, fingers or any other surface. Remember to replace the cap after use. The recommended dose is to place one drop of gel in the corner of the eye, nearest the nose, 3 to 4 times each day and approximately 30 minutes before going to bed.

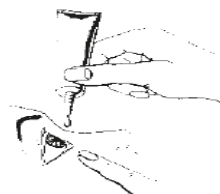
Children and adolescents aged to 18 years

The safety and efficacy of Gel Tears in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data is available.

The amount of gel used should be enough to cover the eye properly.

Follow these instructions carefully.

1. Wash hands thoroughly.
2. Twist off the cap.
3. Look upwards and gently pull down the lower eyelid.
4. Hold the Gel Tears tube just above your eye and gently squeeze until some gel falls into the gap between your eyeball and lower eyelid.
5. Release the lower eyelid, and move your eye while open to ensure the gel covers the eye completely.
6. Repeat the process in the other eye if necessary.



If you use more Gel Tears than you should it is very unlikely that you will suffer an overdose, but if you suddenly feel unwell after using the gel, tell your doctor or eye specialist.

If you forget to use your medicine, use it as soon as you remember and then continue as before.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your eyes may sting a little when the drops are put in. These effects will wear off within a few minutes. Visual disturbance, blurred vision and irritation with prolonged use may occur. A few reports of allergy have been received following use of Gel Tears eye gel. This is due to one of the ingredients in the formulation. If you develop pain, swelling or redness in or around the eyes, you should stop using your medicine and consult your doctor or pharmacist.

- If you experience any other undesirable effects whilst using this medicine, please talk to your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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

5. How to store Gel Tears

- Keep out of the sight and reach of children
- Do not store above 25°C.
- Discard after 28 days of first opening the tube.
- Gel Tears is sterile until first opened. It is important to keep the tube as clean as possible during use.
- Do not use the medicine after the expiry date which is stated on the carton and tube label after 'Exp'. The expiry date refers to the last day of that month.
- Remember if your doctor tells you to stop using this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the drops become discoloured or show any other signs of deterioration, seek the advice of your pharmacist.
- 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 Gel Tears contains

The active ingredient in Gel Tears is carbomer. Each gram of Gel Tears contains 0.2%w/w carbomer.

The other ingredients are: sorbitol, 0.01%w/w benzalkonium chloride, sodium hydroxide and water for injection.

What Gel Tears looks like and contents of the pack

Gel Tears is a sterile colourless and Translucent gel and available as tubes of 10g.

Manufactured by: Dr Gerhard Mann Chem. Pharm. Fabrik GmbH, Brunsbutteler Damm 165/173, 13581 Berlin, Germany.

OR

Laboratoire Chauvin, ZI Ripotier Haut, 07200 Aubenas, France.

Procured from within the EU and repackaged by the Product Licence Holder:

B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Gel Tears® PL 18799/2771



FURTHER INFORMATION

Gel Tears is used for the symptomatic treatment of 'dry eye', which is a dehydration of the surface of the eye resulting from disturbances in tear secretion or tear quality. The dry eye condition can also be caused when it is not possible to close your eyelids either partly or completely.

This condition is so common that one in five patients who go to see an ophthalmologist suffers from a dry eye condition. There are many causes, such as reduced tear production in old age, air-conditioned rooms, computer work, hormonal changes during menopause, etc. Environmental and climatic effects can also play a role in the development of dry eye conditions.

What do we understand by the term 'dry eye'?

During the course of the day we blink 14,000 times on an average. With each blinking motion of the eye, a very thin tear film is distributed over the surface of the eyeball, which keeps it smooth, clean and moist, and protects the eye from pollutants. When the volume or the composition of the tear film is disturbed, desiccation phenomena (drying out) of the cornea and conjunctiva occur and the patient experiences symptoms such as burning, dry eye sensation, gritty feeling, feeling of pressure, and sensitivity to light.

Gel Tears is a soothing gel solution which moistens the eye and provides tear-like lubrication to the eyes and eyelids. The carbomer in Gel Tears increases the thickness of the gel which assists the gel in remaining in contact with the eye for a longer period of time.

Your ophthalmologist prescribed a tear substitute for the alleviation of your complaints. In addition to using the preparation consistently as directed, you should follow the recommendations below:

- Let fresh air into your apartment or house several times a day
- Take care that you drink sufficiently
- Go out into the fresh air frequently
- Do not direct air vents towards your eyes
- Take breaks when working in front of a computer screen.

It is, however, also important that you consult your ophthalmologist regularly for follow-up examinations, because dry eye conditions may lead to a serious disease if they are treated incorrectly or inadequately.

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