

Viscotears[®] Liquid Gel

carbomer (polyacrylic acid)

Patient Information Leaflet

This product will be called Viscotears in this leaflet.

Please read this leaflet carefully before you start to use Viscotears.

It contains important information. Keep the leaflet in a safe place because you may want to read it again.

Do not share these eye drops with anyone else just in case you have an eye infection which you could pass on.

If you have any other questions, or if there is something you don't understand, please ask your pharmacist.

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

In this leaflet:

1. What Viscotears is and what it's used for
2. Things to consider before you start to use Viscotears
3. How to use Viscotears
4. Possible side effects
5. How to store Viscotears
6. Further information

1. What Viscotears is and what it's used for

Viscotears contains the active ingredient, carbomer (polyacrylic acid).

Viscotears is used to make your eyes more comfortable when they feel dry. It is one of a group of eye drops called 'artificial tears'.

2. Things to consider before you start to use Viscotears

DO NOT use Viscotears if:

- If you are allergic to carbomer or any of the other ingredients of this medicine (listed in section 6).

Take special care:

In children and adolescents aged to 18 years, the safety and efficacy of Viscotears at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

Warnings and precautions

- Only use Viscotears in your eye(s).
- If you have problems with your eyes apart from sore or dry eyes talk to your doctor or pharmacist before you start to use Viscotears.
- If you experience eye pain, vision changes, irritation of the eyes, persistent redness, or if the condition worsens or persists, discontinue use and consult your doctor.
- If you are taking other medicines. Please, also read the section "Using other medicines".

Other medicines and Viscotears

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are using other eye drop or eye ointment medicines, wait at least 5 minutes between each medicine. Viscotears should always be the last eye drops used.

Pregnancy and breast-feeding

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 taking this medicine.

Viscotears contains cetrimide

A preservative in Viscotears (cetrimide) may cause eye irritation and is also known to discolour soft contact lenses.

If you wear contact lenses, you should remove them before using Viscotears and wait at least 15 minutes before putting your lenses back in.

Driving and using machines

Some people may find that their vision is blurred immediately after using Viscotears. If affected, wait until your vision clears before you drive or use machinery.

3. How to use Viscotears

If your doctor has prescribed Viscotears he/she will tell you how and when to use it and the dose will be on the pharmacist's label.

The usual dosage is:

Adults (including the elderly): One drop in each affected eye, three or four times a day.

Children and adolescents aged to 18 years:

The safety and efficacy of Viscotears in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available. If you are not sure ask your doctor or pharmacist.

How to use your eye drops

1. Wash your hands.
2. If you wear contact lenses, remove them before using the drops and do not replace for at least 15 minutes.
3. Hold the tube **vertically** (see figure 1).
4. Tilt your head backwards (see figure 2).
5. Rest one hand on your cheek and gently pull down your lower eye lid.
6. Look upwards.
7. Insert one drop by squeezing the tube gently (see figure 3).
8. Blink a few times to spread the liquid gel evenly over your eye.
9. Wipe away any excess gel from around the eyelids.
10. Repeat for your other eye if required.

NOTE: Do not touch your eye or the surrounding area with the tip of the dropper as this may cause injury to the eye and contaminate the gel.

If you use more Viscotears than you should, it is not expected that you will suffer any side effects from this, however, should you notice any problems you think are related, seek medical attention. Follow the instructions carefully. If there is anything you don't understand, ask your pharmacist or doctor.

Do not use Viscotears Liquid Gel later than four weeks after first opening.

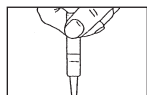


Figure 1



Figure 2



Figure 3

4. Possible side effects

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

You may experience the following reactions in your eyes:

Very common side effects (may affect more than 1 in 10 people): blurred vision

Common side effects (may affect up to 1 in 10 people): eye discomfort, eyelid crusting, eye irritation.

Uncommon side effects (may affect up to 1 in 100 people): eye swelling, eye pain, itchy eye, eye redness, increased tear production.

Or, reactions in other parts of your body:

Uncommon side effects (may affect up to 1 in 100 people): skin inflammation.

Additional side effects from post-marketing experience that have been reported for which the frequency is not known: Allergic reactions (symptoms may include itching, redness, swelling, or pain of the eye or redness, swelling or rash of the skin around the eye).

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 the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Viscotears

Keep all medicines out of the reach and sight of children.

Do not store the drops above 25°C.

Do not use the drops for longer than 28-days after first opening the tube.

Do not use the eye drops after the expiry date shown on the tube (EXP).

Take any unused Viscotears back to your pharmacist to be destroyed. Do not throw it away with your normal household water or waste.

This will help to protect the environment.

6. Further information

Viscotears contains 2.0 mg/g of the active ingredient, carbomer (polyacrylic acid). The liquid gel also contains the inactive ingredients cetrimide (as a preservative), sorbitol, sodium hydroxide and water. Each tube contains 10 g of Viscotears.

The product licence holder and manufacturer responsible for release on to the market is Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
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13581 Berlin, Germany

This leaflet was revised in October 2016.

P1UK02
42540PB296/2-UK