Package Leaflet: Information for the user Carbosol 0.5 % eye drops multidoses

Sodium carboxymethylcellulose

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 have 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 Carbosol 0.5 % eve drops is and what is it used for?
- 2. What you need to know before you use Carbosol 0.5 % eye drops?
- 3. How to use Carbosol 0.5 % eye drops?
- 4. Possible side effects
- 5. How to store Carbosol 0.5 % eye drops?
- 6. Contents of the pack and other information

1. What Carbosol 0.5 % eye drops is and what is it used for?

Pharmacotherapeutic group - ATC code: S01XA20 - Artificial tears

This medicine is used to relieve the signs of irritation due to dry eyes (when the eyes are not producing enough tears)

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 Carbosol 0.5 % eye drops

Do not use Carbosol 0.5 % eye drops

- If you are allergic to carboxymethylcellulose sodium or any other ingredients included in this medicine, mentioned in section 6.

Warning and precautions

Talk to your doctor or, pharmacist before using Carbosol 0.5 % eye drops.

In case of persistence of symptoms, CONSULT AN OPHTHALMOLOGIST so your treatment can be adapted. This eye drops is presented in multidose presentation and contains preservatives.

To avoid any possible contamination or any possible eye damage, do not touch the eye or any surface with the tip of the vial.

A transient visual disturbance can happen at instillation until uniformly spread at the surface of the eye.

Other medicines and Carbosol 0.5 % eye drops

If you are using other concomitant eye drops, leave at least 15 minutes between putting in the other drops and finish by the thicker one. Carbosol 0.5 % eye drops can retain the other medicines absorption, it should be used last if it is the thickest one.

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

Carbosol 0.5 % eye drops with food, drink and alcohol.

No object.

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 using this medicine. Do not exceed the maximum recommended dosage of 1 drop in the eye(s) to be treated up to 8 times per day.

Driving and using machines

Carbosol 0.5 % eye drops may cause temporary blurring of vision after instillation depending on the viscosity of the product. If you do experience temporary blurring, do not drive or use machinery until your sight is clear again.

3. How to use Carbosol 0.5 % eye drops?

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 recommended dose is 1drops/eye of Carbosol 0.5 % eye drops in the affected eye(s), 2 to 4 times a day and up to 8 times a day if dryness symptoms continue.

Method of administration

Local route

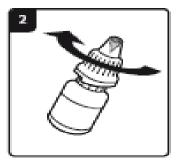
OCULAR INSTILLATION

You do not need to remove your contact lenses before using Carbosol 0.5 % eye drops CARBOSOL. To avoid contamination or injury, avoid contact of the tip of the bottle with your eye or any other surface.

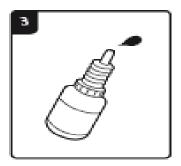
Opening of the bottle:



1. Place the cap, which has a spike, on the top of the bottle.



2. Screw on the cap while pressing it down to pierce the bottle.



3. Dispense the drops by applying gentle pressure to the bottle. Replace the cap after each use.

When using this eye drops, please observe the following steps:

- 1-Wash your hands thoroughly before instillation.
- 2- Avoid contact of the top of the vial with the eye or eyelids.
- 3- Instill one drop into the eye, looking upwards and pulling the lower eyelid slightly downwards.
- 4- Close your eye few seconds
- 5- Once your eye is closed, cleanly wipe off the excess
- 6- Re-cap the bottle after use.

Frequency of administration

Distribute the instillations throughout the day, depending on the needs.

Treatment duration

If symptoms continue or worsen, consult an ophthalmologist so your treatment can be adapted.

If you use more Carbosol 0.5 % eye drops that you should

Please see your doctor or pharmacist.

If you forget to use Carbosol 0.5 % eye drops

Do not use a large number of drops to make up for forgetting to put drops in your eye(s) earlier.

If you stop using Carbosol 0.5 % eye drops

No object.

If you have any further questions on the use of this medicine, ask more information to your doctor, pharmacist.

4. Possible side effects

Like all medicines, Carbosol 0.5 % eye drops can cause side effects, although not everybody gets them.

Common side effects

These side effects can courr in 1 to 9 patients over 100

Eye disorder:

Eye irritation (including burning and discomfort).

Post-Marketing Data

The following side effects have been reported since the drug has been marketed:

Side effects with not known frequency:

- Allergic reactions (including eye or eyelid swelling),
- Increase of eye discharge,
- Pain in the eye,
- Crusting of the eye lid and/or drug residue,
- Impaired vision,
- Eye injury to the surface of the eye due to the tip of the nozzle touching the eye during use and/or superficial cornea trauma,
- Blurred vision,
- Tingling in the eye,
- Feeling that something is in your eye,
- Itchiness of the eye,
- Redness of eye/eyelid, tearing
- Increase tearing.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system. By reporting side effects, you can help provide information on the safety of this medicine.

5. How to store Carbosol 0.5 % eye drops?

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 vial and carton after EXP. The expiry date refers to the last day of that month.

.Store below 30 °C.

Do not use if Carbosol 0.5 % eye drops packaging shows evidence of tampering. Do not use if solution changes colour or becomes cloudy.

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 Carbosol 0.5 % eye drops contains?

- The active ingredient is: carboxymethylcellulose sodium 0.5 %
- The other ingredient are: sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride, stabilised oxychloro complex, boric acid, sodium hydroxide and water for injection.

What Carbosol 0.5 % eye drops looks like and contents of the pack

Carbosol 0.5 % eye drops is a clear, colourless to pale yellow eye drops solution in a 10 mL bottle with a screw cap.

Marketing Authorisation Holder

Exphar SA

Zoning Industriel de Nivelles Sud, zone 2 Avenue Thomas Edison 105 1402 Thines – Belgium

Manufacturer

Ahlcon Parenterals (India) Ltd SP-917-918, Phase-III, Ind. Area, Bhiwadi-301019

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