

Softdrops
Carboxymethylcellulose Sodium and Glycerin 0.5%/0.5% w/v Eye Drops

Patient Information Leaflet

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What Softdrops is and what it is used for
2. What you need to know before you use Softdrops
3. How to use Softdrops
4. Possible side effects
5. How to store Softdrops

1. What Softdrops is and what it is used for

This product contains Carboxymethylcellulose and Glycerin. These are eye lubricants that keeps the eye moist, help to protect the eye from injury and infection, and decrease symptoms of dry eyes such as burning, itching, and feeling as if something is in the eye. This medication is used to relieve dry, irritated eyes. Common causes for dry eyes include wind, sun, heating/air conditioning, computer use/reading, and certain medications.

2. What you need to know before you use Softdrops

Before using this product, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies & if you have eye infection or trauma. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. If you have any health problems, consult your doctor or pharmacist before using this product. Follow all directions on the product package. If you are uncertain about any of the information, consult your doctor or pharmacist.

Warnings & Precautions

For external use only. Keep out of reach and sight of children.

To avoid contamination or possible eye injury, do not touch tip of the bottle or vial to any surface and avoid contact with the eye. Re-cap after use.

Do not use if Softdrops packaging shows evidence of tampering. Do not use if solution changes colour or becomes cloudy.

Discontinue use of Softdrops and consult a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens. Use before the expiration date marked on the container.

If you are also using another kind of eye medication (e.g., drops or ointments), wait at least 5 minutes before applying other medications. Use eye drops before eye ointments to allow the eye drops to enter the eye.

Tell your doctor if your condition persists or worsens after 3 days.

Other medicines

If you are using this product under your doctor's direction, your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor or pharmacist first.

Before using this product, tell your doctor or pharmacist of all prescription and non-prescription /herbal products you may use, especially of: other eye medications

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.

The use of Softdrops is not recommended during pregnancy or breast-feeding. Do not use Softdrops unless clearly indicated by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines until your vision is clear. You may find that your vision is blurred for a time just after using Softdrops. Softdrops may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected, take care when driving or using machines.

3. How to use Softdrops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Only use Softdrops for your eyes. Do not swallow or inject.

Instill 1 or 2 drops in the affected eyes.

Follow the directions on the label. Wash hands

before and after use. Tilt the head back slightly and pull down the lower eyelid with your index finger to form a pouch. Try not to touch the tip of the dropper to your eye, fingertips, or any other surface.

Squeeze the prescribed number of drops (usually one or two drops) into the pouch. Close the eye gently for a few moments to allow the drops to be in contact with the eye. Use your medicine at regular intervals. Do not use your medicine more often than directed.

Talk to your pediatrician regarding the use of this medicine in children. While this medicine may be used in children as young as 6 years for selected conditions, precautions do apply. If you are using other eye drops, leave at least 5 minutes between putting in Softdrops and the other drops. Eye ointments should be administered last.

If you use more Softdrops than you should

If you get too much in your eyes, rinse it all out with warm water. Do not put in any more drops until it's time for your next regular dose.

If you forget to use Softdrops

Use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

Vision may be temporarily blurred when this product is first used. Also, minor burning/stinging/irritation may temporarily occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these unlikely but serious side effects occur: eye pain, change in vision, continued eye redness/irritation.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist

5. How to store Softdrops Eye drops

- Keep out of the reach and sight of children.
- Store below 30°C. Protect from light.
- Throw away any unused medicine after the expiration date.
- Use the solution within one month after opening the vial.

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 Softdrops contains:

Active substances are:

Carboxymethylcellulose Sodium USP 0.5% w/v

Glycerin BP 0.5% w/v

List of Excipients:

Stabilized Oxychloro Complex, N-Acetyl Carnosine, Synthetic Retinol Concentrate (Oily Form) BP, Allrac-Alpha-Tocopheryl Acetate BP, Polyoxyl 35 Castor Oil USP-NF, Boric Acid BP, Sodium Perborate BP, Borax BP, Sodium Citrate BP, Potassium Chloride BP, Magnesium Chloride Hexahydrate BP, Calcium Chloride Dihydrate BP, Sodium Chloride BP, Hydrochloric Acid BP, Sodium Hydroxide BP and Water for Injections BP.

What Softdrops looks like and contents of the pack

Colourless to pale yellow coloured, clear solution. 10 mL solution filled in a LDPE vial Carton containing such one LDPE vial along with HDPE cap and Patient Information Leaflet.

Supplier	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop, Kandivli (West) Mumbai - 400 067, India. Tel: +91-22-6606 1000 Fax: (0091) 22-66061200/ 300 Email:info@ajantapharma.com	Ajanta Pharma Limited Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128.

For any information about this medicinal product, please contact the Supplier.

DATE OF PUBLICATION OR REVISION

Jun 01, 2023