

PACKAGE LEAFLET

EMADINE 0.5 mg/ml Eye Drops, solution. Emedastine

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or your pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.

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 EMADINE is and what it is used for
2. Before you use EMADINE
3. How to use EMADINE
4. Possible side effects
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6. Further information

1. WHAT EMADINE IS AND WHAT IT IS USED FOR

EMADINE is a medicine for the treatment of seasonal allergic conjunctivitis of the eye (allergic conditions of the eye). It works by reducing the intensity of the allergic reaction.

Allergic conjunctivitis. Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

2. BEFORE YOU USE EMADINE

Do not use EMADINE...

- **if you are allergic** to emedastine or any of the other ingredients.

Ask your doctor for advice.

Take special care with EMADINE ...

- **Do not use EMADINE in children under the age of 3 years.**
- **If you wear contact lenses** please see section 'Important information about some of the ingredients of Emadine below'.
- **EMADINE is not recommended** for use in patients over 65 years of age, as it has not been studied in clinical trials in this age group.
- **EMADINE is not recommended** for use in patients with kidney or liver problems.

Using 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 other eye drops at the same time as EMADINE, follow the advice at the end of section 3 “How to use EMADINE”.

Pregnancy and breast feeding

- **If you are pregnant, or might get pregnant**, if you are breast-feeding. Ask your doctor for advice.

Driving and using machines

You may find that your vision is blurred for a time just after you use EMADINE. Do not drive or use machines until your vision is clear.

Important information about some of the ingredients of EMADINE

A preservative in EMADINE (benzalkonium chloride) may cause eye irritation and is known to discolour soft contact lenses. Therefore do not wear contact lenses whilst using EMADINE. Wait 15 minutes after using EMADINE before putting your lenses back in.

3. HOW TO USE EMADINE

Always use EMADINE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to use

Adults and children over 3 years: **One drop in the eye, twice a day.**

Use this much unless your doctor tells you something differently. Use it for as long as your doctor tells you to. Only use drops in both eyes if your doctor tells you to.

Only use the drops in your eyes.

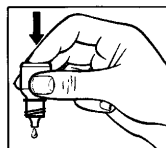
Turn the page for more advice

Now turn over>

3. HOW TO USE EMADINE (continued)



1



2

How much to use

< see side 1

- Get the EMADINE bottle and a mirror.
- Wash your hands.
- Take the bottle and twist off the cap.

- Hold the bottle, pointing down, between your thumb and middle finger.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- **Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops left in the bottle.
- **Gently press on the base** of the bottle to release one drop of EMADINE at a time.
- **Don't squeeze the bottle**, it is designed so that just a gentle press on the bottom is needed (picture 2).
- If you use drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use.

If you accidentally swallow EMADINE or inject it contact a doctor immediately. It may affect your heart rhythm.

If a drop misses your eye, try again.

If you get too much in your eyes, rinse it all out preferably with sterile saline or, if not available, with warm water. Don't put in any more drops until it's time for your next regular dose.

If you forget to use EMADINE, use one drop as soon as you remember, and then go back to your normal routine. **Do not use a double dose** to make up for the one missed.

If you are using other eye drops, leave at least 10 minutes between using EMADINE and the other drops.

4. POSSIBLE SIDE EFFECTS

Like all medicines EMADINE can cause side effects although not everyone gets them. These can be unpleasant, but most of them disappear quickly.

You can carry on taking the drops, unless the effects are serious, If you are worried, talk to your doctor or pharmacist.

Common side effects

(affects 1 to 10 users in 100)

Effects in the eye: eye pain, eye irritation, blurred vision, corneal staining, dry eye, itchy eye, eye redness

General side effects: headache

Uncommon side effects

(affects 1 to 10 users in 1,000)

Effects in the eye: corneal disorder, abnormal eye sensation, increased tear production, tired eyes

General side effects: difficulty sleeping, sinus headache, bad taste, rash

Not Known

(frequency cannot be estimated from the available data)

General side effects: increased heart rate

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

5. HOW TO STORE EMADINE

Keep out of the reach and sight of children.

Do not use EMADINE after the expiry date which is stated on the bottle and box after “EXP”. The expiry date refers to the last day of the month.

Do not store above 25°C.

You must throw away the bottle four weeks after you first opened it, to prevent infections. Write down the date you opened each bottle in the space below and in the space on the bottle label and box.

Opened:

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 protect the environment.

6. FURTHER INFORMATION

What EMADINE contains

The active substance is emadastine 0.5 mg/ml as difumarate.

The other ingredients are: benzalkonium chloride, trometamol; sodium chloride; hypromellose; purified water. Tiny amounts of hydrochloric acid or sodium hydroxide are sometimes added to keep acidity levels (pH levels) normal

What EMADINE looks like and the contents of the pack

EMADINE is a liquid (a solution) supplied in a pack containing a 5 ml or 10 ml plastic (DROP-TAINER) bottle with a screw cap. Not all pack sizes may be marketed.

The marketing authorisation holder

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Detailed information on this medicine is available on the European Medicines Agency website:
www.ema.europa.eu