

PACKAGE LEAFLET: INFORMATION FOR THE USER

MAROCEN

0.3 % w/v eye drops, solution

CIPROFLOXACIN (AS HYDROCHLORIDE)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 or pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What MAROCEN is and what it is used for
2. Before you take MAROCEN
3. How to take MAROCEN
4. Possible side effects
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1. WHAT MAROCEN IS AND WHAT IS IT USED FOR

MAROCEN belongs to a group of medicines known as quinolone antibiotics. Bromhexine facilitates expectoration and reduces cough.

It is used for the treatment of corneal ulcers and some other bacterial infections of the eye(s).

2. BEFORE YOU TAKE MAROCEN

Do not take MAROCEN

- If you are allergic (hypersensitive) to ciprofloxacin or any other quinolone antibiotic or to any of the other ingredients.

Ask your doctor for advice.

Take special care with MAROCEN

- Only use MAROCEN in your eyes.
- Only use MAROCEN in children younger than 1 year if prescribed by your doctor.

- As with any antibiotic, use of MAROCEN for a long time may lead to other infections. If your symptoms get worse or suddenly return tell your doctor. You may become more susceptible to other infections with the use of this medicine, especially after prolonged use.
- If you notice the first signs of a skin rash or any other allergic reaction, including hives, itching, breathing problems stop treatment and immediately contact your doctor. If you have a serious allergic reaction then you may need emergency treatment.
- If you feel pain, swelling or inflammation while or shortly after taking this medicine, stop treatment and contact your doctor.
- If you are elderly or if you are taking medicines called 'corticosteroids' used to treat conditions such as pain and inflammation, asthma or skin problems then you have a higher risk of getting tendon problems during treatment with MAROCEN. If you experience any inflammation or inflammatory condition, stop treatment and immediately consult your doctor.

Taking other medicines

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 more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, talk to your doctor before you use MAROCEN.

Driving and using machines

If your sight is temporarily blurred or affected in any way following use of MAROCEN you should not drive or operate machinery until your vision is clear again.

Important information if you wear Contact Lenses

There is a preservative in MAROCEN (benzalkonium chloride) that may cause eye irritation and can discolour soft contact lenses.

Do not wear contact lenses (hard or soft) during treatment with MAROCEN. If you do continue to wear your lenses, you must remove them before using MAROCEN and wait at least 15 minutes after use before putting your lenses back in.

3. HOW TO USE MAROCEN

The usual dose

This will depend on whether you are being treated for corneal ulcers or for some other bacterial infection in your eye.

Corneal Ulcers

Dosing is continued during the night time. Day 1 - 2 drops every 15 minutes for the first 6 hours and then 2 drops every 30 minutes.

Day 2 - 2 drops every hour.

Day 3 to Day 14 - 2 drops every 4 hours. Your doctor will tell you if treatment needs to be continued for longer than 14 days.

Other bacterial infections

1 or 2 drops 4 times a day. For severe infections the dose for the first 2 days may be increased to 1 or 2 drops every 2 hours, while you are awake.

It is important that you continue to use MAROCEN for the full treatment period as advised by your doctor even if your symptoms improve. If you stop using this medicine too early, your symptoms may re-occur.

You should not use MAROCEN for more than 21 days, unless your doctor says otherwise.

Remove the loose collar from the cap when the bottle is first opened.

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

How to use

- Wash your hands before you start.
 - Twist off the bottle cap.
 - Hold the bottle pointing down, between your thumb and fingers.
 - Tilt your head back.
 - Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here.
 - Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
 - Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
 - Gently press on the base of the bottle to release one drop at a time.
 - Do not squeeze the bottle, only a gentle press on the bottom is needed.
 - If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.
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- If a drop misses your eye, try again.
 - If you forget to use MAROCEN, do not worry, just use it when it is next due. Do not take a double dose to make up.
 - If you use more MAROCEN than you should it can be washed out of your eye with lukewarm water.
 - If this medicine is accidentally swallowed, it is not likely to cause any serious problems, but contact your doctor.

If you have any further questions on the use of MAROCEN, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

- You may experience some or all of the following effects in your eye(s):

Common (1 to 10 users in 100): White deposits on the eye surface (cornea), discomfort (stinging or burning, gritty feeling in the eye, irritation), redness.

Uncommon (1 to 10 users in 1,000): Damage to the eye surface (cornea), sensitivity to light, blurred vision, swelling of the eye or eyelid, pain, dry eye, itchiness, eye discharge, eyelid crusting, eyelids scales, eyelid redness, poor vision, watery eyes, red eyes

Rare (1 to 10 users in 10,000): Damage of the eye, inflammation, double vision, decreased eye sensation, tired eyes, stye.

If you notice white particles in your eyes, continue to use MAROCEN but tell your doctor immediately.

- You may also experience effects in other areas of your body including:

Common: Bad taste.

Uncommon: Headache, nausea.

Rare: Hypersensitivity, dizziness, ear pain, inflammation inside the nose, nasal sinus discharge, diarrhoea, abdominal pain, skin inflammation, tendon disorder.

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.

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

If you experience an allergic reaction, stop using MAROCEN and tell your doctor.

5. HOW TO STORE MAROCEN

- Keep out of the reach and sight of children.
- Do not store above 25° C.
- Do not refrigerate or freeze.
- Keep the bottle tightly closed.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
 - Stop using the bottle 28 days after first opening, to prevent infections.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours