Package Leaflet: Information for the user Vividrin Hayfever 2 % w/v Eye Drops, solution Sodium cromoglicate

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 pharmacist has 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- -- You must talk to your doctor if your eyes do not feel better or if they feel worse after 2 days.

What is in this leaflet

- 1. What Vividrin is and what it is used for
- 2. What you need to know before you use Vividrin
- 3. How to use Vividrin
- 4. Possible side effects
- 5. How to store Vividrin
- 6. Contents of the pack and other information

1. What Vividrin is and what it is used for

Vividrin contains the active substance sodium cromoglicate. This belongs to a group of medicines called anti-allergics. Vividrin is used for the relief and treatment of the eye symptoms of hayfever (which is an allergic condition) such as red, sore, itchy and watery eyes.

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 Vividrin Do not use these drops

-- If you are allergic (hypersensitive) to sodium cromoglicate or any of the other ingredients of this medicine including benzalkonium chloride (listed in section 6).

Warnings and precautions

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- -- Do not use if the bottle has been opened before you are given it.
- -- Throw the bottle away 1 month after first opening it or if the solution stops looking clear.

Other medicines and Vividrin

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

Pregnancy and breastfeeding

-- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

-- Vividrin can cause stinging and blurring of vision when first used. Do not drive or operate machinery until proper vision is restored.

Vividrin contains benzalkonium chloride

This medicine contains 0.00306 mg benzalkonium chloride in each drop (0.0306ml) which is equivalent to 0.1 mg/1 ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Vividrin

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure. If your eyes are no better after 2 days of using the eye drops, see your doctor or pharmacist. If you find you need to use the drops continuously for more than 14 days, then check with your pharmacist or doctor before continuing.

Dosage

Unless otherwise prescribed, the dose for adults and children over 6 years is 1 or 2 drops into each eye 4 times daily.

Apply your eye drops in the following way:

- 1. Before using your Vividrin Hayfever Eye Drops you should wash your hands.
- 2. You may find it helps to sit in front of a mirror, so that you can see what you are doing. Tilt your head backwards, gently pull down your lower eyelid and carefully place one or two Vividrin Hayfever Eye Drops in the space between the eyelid and the eye. Take care not to touch the dropper with your eye or fingers.
- 3. Release the eyelid and blink a few times to make sure the liquid covers the whole surface of the eye.
- 4. Repeat the procedure with the other eye and then replace the cap on the bottle.

If you use more Vividrin than you should

If you use more Vividrin than you should contact your doctor or pharmacist.

If you forget to use Vividrin

Use your drops as soon as you remember and then carry on in the usual way. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any difficulty stop using your drops and talk to your doctor or pharmacist. The following side effects may occur:

- Like with all eye drops, you may have a brief blurring of vision or a slight stinging feeling after using the drops.
- Irritation or itching of the eye may occur in a very small number of people.

Talk to your doctor or pharmacist if any of the side effects become serious or last longer than a few days, or if you notice any side effects not listed in this leaflet.

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:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Vividrin

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 carton and label. The expiry date refers to the last day of that month.
- -- Do not use the eye drops more than four weeks after first opening the bottle. Discard any unused medicine after this time.
- -- Do not use this medicine if you notice the solution is cloudy. Store below 25°C. Keep bottle in outer carton to protect from light.

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 Vividrin contains

- -- The active substance is Sodium Cromoglicate.
- -- The other ingredients are Benzalkonium Chloride, Edetic Acid Disodium Salt, Polysorbate, Sorbitol, Sodium Hydroxide and Purified Water.

What Vividrin looks like and contents of the pack

Your eye drops are sterile preserved multidose eye drops and are supplied in plastic bottles. Each bottle has a volume of 10.0 ml. The eye drops are a clear solution.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is: Bausch & Lomb UK Limited 106 London Road Kingston-Upon-Thames Surrey, United Kingdom KT2 6TN

The Manufacturer is:

Dr. Gerhard Mann Chem-pharm. Fabrik GmbH Brunsbütteler Damm 165/173 13581 Berlin Germany

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