

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vividrin®

Antiallergic Eye Drops, Solution 2% w/v

Sodium cromoglicate

The name of your medicine is Vividrin Antiallergic Eye Drops, Solution 2% w/v and it is called Vividrin Eye Drops in this leaflet.

Please read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to use Vividrin Eye Drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT VIVIDRIN EYE DROPS ARE AND WHAT THEY ARE USED FOR

Your drops contain the active ingredient sodium cromoglicate, which belongs to a group of medicines called antiallergics. Your drops are used to prevent and treat chronic allergic conjunctivitis and hay fever (acute allergic conjunctivitis).

Allergic conjunctivitis is an inflammation of the thin skin that covers the white parts of the eyes and the inside of the eyelids. The most common cause is an allergy to pollen during the hay fever season. Other causes are less common such as allergies to house dust mites, cosmetics or problems with contact lenses. You may have red, watery and itchy eyes.

The sodium cromoglicate in your drops works to stop the allergic reaction in your eyes and has a soothing effect.

These drops can be used in children, adults and the elderly.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VIVIDRIN EYE DROPS

Do NOT use these drops

- If you have been told, or know, that you are allergic (hypersensitive) to any of the ingredients (see Section 6 and end of Section 2).

Take special care with these drops

- If you wear soft contact lenses – see end of Section 2 (Important information about some of the ingredients).

Taking 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.

Pregnancy and breast-feeding

- Use these drops only if necessary, and then only on your doctor's advice, if you are pregnant or breast-feeding.
- Vividrin eye drops should not be used during the first 3 months of pregnancy.

Driving and using machines

- All eye drops can cause a short term blurring of vision when first used so you should wait until your eyes are clear before driving or using machines.

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.

Vividrin contains Polysorbate

Vividrin contains polysorbate which can cause allergic reactions.

3. HOW TO USE VIVIDRIN EYE DROPS

To work best, these drops should be used every day that you are in contact with the allergen (pollen, house dust, cosmetics) even when you are not suffering from any symptoms. If your symptoms are caused by pollen, you should continue to use your drops until the end of the hayfever season.

If you have used sodium cromoglicate before, you may have to take it for a few days before you obtain the maximum effect.

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

The medicine is to be used only as drops applied into the eye.

Dosage

The usual dose is 1 drop in each eye, 4 times each day. Your doctor may tell you to use your drops more often if you are in contact with high pollen levels.

You may find it easier to remember to take them if you use them at meal times and before going to bed.

Directions for use

- Wash your hands before using your drops
- Sit down in front of a mirror so that you can see what you are doing
- Pull your lower eyelid gently down, and then carefully place one drop in the space between the eyelid and eye (see picture)
- Take care not to touch the dropper with your eye or fingers
- Release the lower eyelid, and blink a few times to make sure the eye is covered by the liquid
- Repeat the procedure for your other eye
- Put the cap back on the bottle



If you use more Vividrin Eye Drops than you should

If you accidentally use too much, do not worry.

If you forget to use Vividrin Eye Drops

Use your drops as soon as you remember 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vividrin Eye Drops can cause side effects, although not everybody gets them. Like all eye drops you may briefly have blurred vision or a slight stinging feeling after using your drops.

There is also a slight possibility that irritation of the eye may occur in a very small number of people. Very rarely, an allergic reaction can occur. Symptoms include facial rash, swelling around the eye and very rarely difficulty in breathing.

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:

HPRA Pharmacovigilance.

Website: www.hpra.ie

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

5. HOW TO STORE VIVIDRIN EYE DROPS

- Keep out of the reach and sight of children.
- **Do not use this medicine after its expiry date.**
- **Check the expiry date on the label before you begin to use your medicine.**
- **The expiry date refers to the last day of that month.**
- **If the expiry date has passed, take the medicine back to your pharmacist.**
- Do not store your eye drops above 30°C.
- Keep the bottle in the outer box.
- Your eye drops are sterile until first opened. It is important to keep the drops as clean as possible during use.
- Throw away any remaining drops 4 weeks after first opening the bottle.
- 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 Vividrin Eye Drops contains

- The active ingredient is: sodium cromoglicate 2% w/v. Each 1 ml of solution contains 20mg of sodium cromoglicate.
- The other ingredients are: benzalkonium chloride (see end of Section 2 for further information), disodium edetate, polysorbate 80, sorbitol, sodium hydroxide and water for injection.

What Vividrin Eye Drops looks like and contents of the pack

These eye drops are a colourless to slightly yellow, clear sterile solution and are supplied in plastic bottles. Each

bottle has a volume of 5, 10 or 13.5 ml. Not all bottle sizes may be marketed.

Marketing Authorisation Holder

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