PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

VIVIDRIN EYE DROPS

2,0 % Eye drops, solution

Sodium Cromoglicate

Read all of this leaflet carefully because it contains important information for you

VIVIDRIN EYE DROPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, 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.
- Do not share VIVIDRIN EYE DROPS with any other person.
- Ask your health care provider of pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 2 days.

What is in this leaflet

1. What VIVIDRIN EYE DROPS is and what it is used for
2. What you need to know before you use VIVIDRIN EYE DROPS
3. How to use VIVIDRIN EYE DROPS
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1. What VIVIDRIN EYE DROPS is and what it is used for

VIVIDRIN EYE DROPS contain the active substance sodium cromoglicate. This belongs to a group of medicines called anti-allergics.

VIVIDRIN EYE DROPS is used for the treatment of allergic conjunctivitis (red, sore, itchy and watery eyes).

2. What you need to know before you use VIVIDRIN EYE DROPS

Do not use VIVIDRIN EYE DROPS:

- if you are hypersensitive (allergic) to sodium cromoglicate or any of the other ingredients of VIVIDRIN EYE DROPS (listed in section 6).

Warnings and precautions

- 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 EYE DROPS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy and breastfeeding

Safety in pregnancy has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

VIVIDRIN EYE DROPS may cause stinging or blurring of vision when first used. If you experience blurred vision, wait until your vision clears before driving or using machinery.

VIVIDRIN EYE DROPS contain benzalkonium chloride

This medicinal product contains 0,00306 mg benzalkonium chloride in each drop (0,0306 ml) which is equivalent to 0,1 mg/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 VIVIDRIN EYE DROPS 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 VIVIDRIN EYE DROPS, talk to your doctor.

Vividrin contains Polysorbate

Vividrin contains polysorbate which can cause allergic reactions.

3. How to use VIVIDRIN EYE DROPS

Always use VIVIDRIN EYE DROPS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children is: 1-2 drops into each eye 4 times daily.

You should use the eye drops regularly, as therapy with VIVIDRIN EYE DROPS is essentially prophylactic (used to prevent eye allergies).

Apply your eye drops in the following way:

1. Before using your VIVIDRIN 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 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 EYE DROPS than you should

In the event of overdosage, or if someone accidentally swallowed the eye drops, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use VIVIDRIN EYE DROPS

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

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

4. Possible side effects

VIVIDRIN EYE DROPS can have side effects.

Not all side effects reported for VIVIDRIN EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VIVIDRIN EYE DROPS, please consult your health care provider for advice.

You may briefly have blurred vision or a slight stinging feeling after using your drops. There is also a slight possibility that irritation or itching of the eye may occur in a very small number of people.

In hypersensitive (allergic) persons, side effects may include headache, skin rash, bronchospasm, breathlessness, or anaphylaxis (which is a serious allergic reaction).

If you experience any of these symptoms, stop using VIVIDRIN EYE DROPS and tell your doctor or pharmacist immediately.

If you experience any swelling of the mouth or throat, which prevents you from breathing normally, go to the casualty department at your nearest hospital.

These are very serious side effects. If you have them, you may have had a serious reaction to VIVIDRIN EYE DROPS. You may need urgent medical attention or hospitalisation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of VIVIDRIN EYE DROPS.

5. How to store VIVIDRIN EYE DROPS

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the bottle in the outer carton to protect from light.
- Do not use the eye drops after the expiry date which is stated on the carton and label.

- Do not use the eye drops more than 1 month after fist opening the bottle. Discard any unused medicine after this time.
- Do not use this medicine if you notice the solution is cloudy.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VIVIDRIN EYE DROPS contain

- The active substance is sodium cromoglicate 20,0 mg per 1 ml (2,0 % w/v).
- The preservative is benzalkonium chloride 0,01 % w/v.
- The other ingredients are disodium edetate, polysorbate 80, sorbitol, sodium hydroxide solution (for pH adjustment) and water for injection.

What VIVIDRIN EYE DROPS look like and contents of the pack

VIVIDRIN EYE DROPS is a clear, non-viscous, slightly yellow solution.

It is supplied in a white plastic bottle containing 10 ml of solution, with a tamper-proof white cap.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website,

www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.