PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

VIVIDRIN EYE DROPS

2,0 % *w/v* Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium cromoglicate (equivalent to 20,0 mg/ml anhydrous sodium cromoglicate).

(Sodium cromoglicate 2,0 % *w/v*)

Excipient with known effect: Benzalkonium chloride 0,01 % *w/v* (preservative)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

A clear, non-viscous, slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic conjunctivitis.

4.2 Posology and method of administration

Posology

For adults and children: 1-2 drops into each eye 4 times daily.

Since therapy with sodium cromoglycate is essentially prophylactic, it is important to instruct patients to maintain regular dosage.

4.3 Contraindications

Hypersensitivity to the active substance sodium cromoglicate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The solution should be discarded 1 month after first opening the bottle or if any turbidity develops. Do not use if the bottle has been opened prior to receipt.

Where concomitant steroid and sodium cromoglicate treatment has rendered it possible to reduce the steroid dose, precautions must be taken to prevent a severe attack if/when sodium cromoglicate is withdrawn from the treatment regime.

VIVIDRIN EYE DROPS contains 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. Patients should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. VIVIDRIN EYE DROPS should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy has not been established.

4.7 Effects on ability to drive and use machines

Transient stinging or blurred vision may occur on instillation. Do not drive or operate machinery until proper vision is restored.

4.8 Undesirable effects

Transient stinging and blurring may occur after instillation, other symptoms of local irritation have been reported rarely.

Side effects in hypersensitive persons may include headache, skin rash, bronchospasm, breathlessness, anaphylaxis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

Suspected adverse reactions may also be reported directly to the Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com

4.9 Overdose

As sodium cromoglicate is absorbed only to a very limited extent from eye drops, no action other than medical observation should be necessary. In the event of accidental ingestion, symptomatic treatment is recommended.

If a hypersensitive reaction occurs, withdraw treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic Preparations – Other

Sodium cromoglicate has neither anti-histaminic nor anti-inflammatory activity. Evidence suggests that sodium cromoglicate inhibits the release of mediators of the allergic reaction by stabilising the membranes of sensitised mast cells.

5.2 Pharmacokinetic properties

Due to lipid insolubility, sodium cromoglicate is poorly absorbed following administration to the eye. In normal volunteers approximately 0,03 % is systemically absorbed. Absorbed sodium cromoglicate is excreted unchanged in the bile and urine.

Trace amounts of sodium cromoglicate have been detected in the aqueous humour of rabbits for up to 24 hours after treatment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride, disodium edetate, polysorbate 80, sorbitol, sodium hydroxide solution (for pH adjustment), water for injection.

6.2 Incompatibilities

Sodium cromoglicate forms insoluble complexes with metal ions resulting in solution turbidity.

6.3 Shelf life

Unopened: 36 months

Once opened for the first time: 30 days

6.4 Special precautions for storage

Store at or below 25 °C. Discard 30 days after opening.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

White plastic bottle containing 10 ml of solution. Tamper-proof white cap.

6.6 Special precautions for disposal and other handling.

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

W/15.4/86

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/05/1989

10 DATE OF REVISION OF THE TEXT

28 January 2022