Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vividrin Antiallergic Eye Drops, Solution 2% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 20.0 mg of sodium cromoglicate.

Excipient with known effect: Benzalkonium Chloride (0.01%)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops solution
Colourless to slightly yellow, clear, aqueous eye drops solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acute or chronic allergic conjunctivitis e.g. hay-fever conjunctivitis (vernal [kerato-] conjunctivitis).

4.2 Posology and method of administration

Instill one drop into each eye four times a day or as directed by the physician in the case of high pollen challenge. The dose applies equally to children and adults.

Treatment with Vividrin Antiallergic Eye Drops should be continued even after the complaints have disappeared as long as the patient is exposed to the allergizing substances (pollen, house dust, fungus spores, etc.).

4.3 Contraindications

Vividrin Antiallergic Eye Drops are contra-indicated in persons who have shown hypersensitivity to any component of this product.

4.4 Special warnings and precautions for use

Vividrin Hayfever Eye Drops contains benzalkonium chloride
This medicinal product contains 0.00306 mg benzalkonium chloride in each drop (0.0306ml) 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 Hayfever 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 medicinal products and other forms of interactions

None known so far.

4.6 Fertility, pregnancy and lactation

Although there has been no evidence of any embryotoxic effect, Vividrin Antiallergic Eye Drops should, if possible, not be used during the first three months of pregnancy.

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

Irritation of the eye can occur infrequently. Allergic reactions can be observed in isolated cases following treatment with cromoglycic acid/sodium cromoglicate.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Not relevant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cromoglycic acid is used as disodium salt (DSCG = disodium cromoglycate; sodium cromoglycate (British Pharmacopoeia)). Animal experiments and *in vitro* studies have shown that this substance is able, after antigen challenge, to inhibit sensitized mast cell degranulation and thus the release of inflammatory mediators. This mast-cell stabilizing effect has also been observed in humans with antigen-induced and IgE-mediated bronchospasm or in cases of allergic rhinitis. Immediate allergic reactions are correlated in particular with histamine. Sodium cromoglicate blocks the calcium channel linked with the IgE-receptor; it thus inhibits the calcium influx into the mast cell mediated via this receptor, and hence mast cell degranulation. Sodium cromoglicate is bound specifically to a sodium cromoglicate-binding protein, which is part of the IgE-dependent calcium channel. This mode of action applies similarly to all mucous membranes (e.g. bronchi, nose, eye, intestine).

5.2 Pharmacokinetic properties

Sodium cromoglicate is very poorly absorbed from the gastro-intestinal tract. Only about 1% of a dose is absorbed in humans via the gastro-intestinal tract. Less than 7% of an intranasal dose of sodium cromoglicate is absorbed systemically. Plasma protein binding is about 63-76%. The volume of distribution is 0.13 l/kg.

Sodium cromoglicate administered intravenously (slow infusion over 30 minutes) is, on the other hand, eliminated rapidly (half-life about 13.5 minutes); the substance is eliminated almost completely after one hour.

Sodium Cromoglicate is sparingly fat-soluble and is therefore not able to penetrate most of the biological membranes such as the blood-brain barrier. The concentration achieved in the respective target organ following topical application is the exclusive crucial factor for therapeutic efficacy. Metabolic degradation of sodium cromoglicate has not been demonstrated so far; the substance is excreted almost equally divided between urine and bile.

5.3 Preclinical safety data

In rats, dose-related impairment of renal function and even deaths occurred following subcutaneous injection of > 30 mg/kg sodium cromoglicate over a period of 90 days. Neither histological abnormalities in any organ nor any effect on kidney or liver

function could be seen below 30 mg/kg. The biochemical parameters remained unchanged as well. In rhesus monkeys no evidence of impairment was observed after daily doses of 50 mg/kg given over a period of six months.

Teratogenicity tests were performed in mice and rabbits. Up to a high dose of 500-540 mg/kg sodium cromoglicate administered during pregnancy, no foetal malformations could be observed. Some rabbits died, however, under this high dose. All surviving animals developed renal lesions. The mating behaviour and fertility of male and female rats were not affected during 14 day use of sodium cromoglicate.

Experience gathered so far shows no evidence of any mutagenic or carcinogenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Polysorbate 80
Sorbitol
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.

Discard any remaining eye drops within four weeks of first opening the container.

6.4 Special precautions for storage

Do not store above 30°C. Keep container in the outer carton.

Discard 4 weeks after first opening.

6.5 Nature and contents of container

A polyethylene dropper bottle fitted with a polypropylene cap.

Pack sizes: 5, 10, and 13.5 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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Dublin 24
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 26 March 2006

10 DATE OF REVISION OF THE TEXT

January 2022