Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vividrin Preservative Free SDU 2% w/v Eye Drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium cromoglicate 2% w/v.

Each individual single-dose unit contains 10mg of sodium cromoglicate in 0.5ml of solution.

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 for single use.

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

The usual dose is to instil one drop into each eye four times a day or as directed by the physician in the case of high pollen challenge.

Children aged 16 and under – there is no need to adjust the dose.

The elderly – there is no need to adjust the dose.

Treatment with Vividrin Preservative Free SDU should be continued even after the complaints have disappeared as long as the patient is exposed to the alergising substances (pollen, house dust, fungus spores etc.).

4.3 Contraindications

Vividrin Preservative Free SDU are contra-indicated in persons who have shown hypersensitivity to any component of this product.

4.4 Special warnings and precautions for use

None.

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 Preservative Free SDU 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.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cromoglycic acid is used as disodium salt (DSCG*). 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 0.131/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

Sorbitol (E420)
Hypromellose
Hydrochloric acid
Water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C. Keep container in the outer carton.

6.5 Nature and contents of container

Single dose container composed of low density polyethylene (LDPE).

Pack sizes:
20 x 0.5 ml
30 x 0.5 ml
60 x 0.5 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

For single use only. Discard any remaining contents.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA23259/005/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 31 March 2010

10 DATE OF REVISION OF THE TEXT

January 2022