Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vividrin Nasal Spray, Solution 2% w/v Against Hay Fever

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 20.0 mg of sodium cromoglicate.

Each spray contains 2.8mg of sodium cromoglicate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution
A colourless to slightly yellow, clear, aqueous nasal spray solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Perennial allergic rhinitis, seasonal allergic rhinitis (hay fever).

4.2 Posology and method of administration

Unless otherwise prescribed, the dose for adults and children is one squirt of the spray in each nostril four times a day.

Treatment with Vividrin Nasal Spray Against Hay Fever 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 Nasal Spray Against Hay Fever is 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 interaction

None known so far.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known so far.

4.8 Undesirable effects

Mild transient irritation of the nasal mucosa may occur occasionally, rare cases of headache and gustatory irritation are possible. Nosebleed, ulceration of the mucous membrane, swelling of the tongue, cough, and dyspnoea may occur in isolated cases. Allergic reactions were observed in isolated cases following treatment with cromoglycic acid/sodium cromoglicate.

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

Disodium edetate
Polysorbate 80
Sorbitol
Sodium hydroxide (for pH adjustment)
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.
Opened: Discard contents 6 weeks after initial use

6.4 Special precautions for storage

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

6.5 Nature and contents of container

A polyethylene bottle fitted with a nosepiece and spray pump and polypropylene cap.

The volume content is 15 ml.

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

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8 MARKETING AUTHORISATION NUMBER

PA 555/5/1

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