Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rynacrom Nasal Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Cromoglicate 1.6 mg per dose (2 drops).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Nasal drops, solution
Clear colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rynacrom Nasal Drops are indicated for the prevention of allergic rhinitis (seasonal and perennial).

4.2 Posology and method of administration

Adults and Children: Two drops (1.6 mg of sodium cromoglicate) into each nostril 6 times daily.

Rynacrom should be used regularly to ensure optimal control of symptoms. It is recommended that treatment is continued during the period of exposure to the allergen, even when free of symptoms.

4.3 Contraindications

Rynacrom is contraindicated in patients with known sensitivity to sodium cromoglicate or any of the other ingredients.

4.4 Special warnings and precautions for use

1. The product is for nasal use only.
2. Use of medication should be continued even in the absence of symptoms during exposure to the allergen.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Cumulative experience with sodium cromoglicate suggests that it has no adverse effects on foetal development. However, it should be used in pregnancy only if there is a clear need.

On the basis of animal studies it physiochemical properties, sodium cromoglicate is considered unlikely to pass into human breast milk. There is not information to suggest that use of sodium cromoglicate by nursing mothers has any undesirable effects on the baby.

4.7 Effects on ability to drive and use machines

Rynacrom has no known effect on the ability to drive or operate machinery.

4.8 Undesirable effects

Occasional local irritation of the nasal mucosa may occur during the first days of use. Other side effects can include bad taste, headache and nausea and in rare cases wheezing or tightness of the chest have been reported by patients.

4.9 Overdose

No action other than medicinal supervision should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium cromoglicate inhibits the release of mediators of the allergic reaction from sensitised mast cells. In the nose the inhibition of mediator release prevents the symptoms of rhinitis.

5.2 Pharmacokinetic properties

After instillation of Rynacrom Nasal Drops into the nose, less than 7% of the total administered is absorbed via the nasal mucosa. This fraction is excreted unchanged in the bile and urine. The remainder of the dose is expelled from the nose, or swallowed and excreted via the alimentary tract.

5.3 Preclinical safety data

Animal studies have shown that sodium cromoglicate has a very low order of local or systemic toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Benzalkonium chloride
Purified water

6.2 Incompatibilities

None known.
No other medicaments should be mixed with the solution.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C.
Keep the bottle in the outer carton.

6.5 Nature and contents of container

Rynacrom Nasal Drops is presented in a 13.5 ml LDPE bottle fitted with a dropper and screw cap.

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

Fisons Plc.
RPR House
50 Kings Hill Avenue
West Malling
Kent
ME19 4AH
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 18/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 March 1976

Date of last renewal: 12 February 2005

10 DATE OF REVISION OF THE TEXT

April 2005