Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rynacrom 4% w/v Nasal Spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 40 mg sodium cromoglicate delivering 5.2mg sodium cromoglicate per metered dose.
Excipients: Benzalkonium Chloride 0.01% w/v.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution
Colourless or pale yellow, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rynacrom 4% Nasal Spray is indicated for the preventative treatment of allergic rhinitis (seasonal and perennial).

4.2 Posology and method of administration

Adults and Children: One spray into each nostril two to four times daily.

Since Rynacrom 4% Nasal Spray is essentially preventative, it is important to maintain regular dosage, as distinct from using the drug intermittently to relieve 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 intranasal 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. It should only be used in pregnancy where there is a clear need.

On the basis of animal studies and its physiochemical properties, sodium cromoglicate is considered unlikely to pass into human breast milk. There is no 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 effects on the ability to drive or operate machinery.

4.8 Undesirable effects

Occasional 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 medical 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 Spray into the nose, less than 7% of the total dose administered is absorbed via the nasal mucosa. This fraction is excreted unchanged in the bile and urine. The remainder 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

Not applicable.

6.3 Shelf Life

Unopened: 3 years.
Opened: once opened use within one month.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

White, high-density polyethylene bottle fitted with polypropylene metered dose pump and cap and packaged in an outer box.

Pack size: 22 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

If the nasal spray is new, it should be primed by pressing the nozzle downwards and releasing it at least 3 times until a fine spray of Rynacrom is produced.

Detailed instructions for use are contained in the Patient Information Leaflet supplied with each pack.

7 MARKETING AUTHORISATION HOLDER

Fisons Limited
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West Malling
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8 MARKETING AUTHORISATION NUMBER

PA 18/3/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 February 1991

Date of last renewal: 27 February 2006

10 DATE OF REVISION OF THE TEXT

March 2006