Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nalcrom 100 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Sodium Cromoglicate 100.0 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard
No. 2 clear hard gelatin capsule printed “Sodium Cromoglicate 100 mg” and containing a white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Nalcrom is indicated for food allergy (where adequate investigations have been performed to determine sensitivity to one or more ingested allergens) in conjunction with restriction of main causative allergens.

4.2 Posology and method of administration

Nalcrom must be administered orally.

Adults (including the elderly)
Initial dose: 2 capsules four times daily before meals.

Children (2 – 14 years)
Initial dose: 1 capsule four times daily before meals.

For adults (including the elderly) and children, if satisfactory control is not achieved within two to three weeks, the dosage may be doubled but should not exceed 40 mg/kg/day.

Maintenance dose: Once a therapeutic response has been achieved, the dose may be gradually reduced to the minimum required to maintain the patient free from symptoms.

4.3 Contraindications

Nalcrom is contraindicated in patients with a known hypersensitivity to sodium cromoglicate.

4.4 Special warnings and precautions for use

(A) General summary of the most important side effects:

Side effects include nausea, vomiting, diarrhoea, abdominal discomfort, rashes and joint pains.

(B) Special precautions for use.

1. There is insufficient experience to assess safety of long term use over more than 1 year.

2. Patients with a history of anaphylactic shock or similar life-threatening reactions to foods should not rely upon Nalcrom to protect them.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

As with all medication caution should be exercised especially during the first trimester of pregnancy. 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.

It is not known whether sodium cromoglicate is excreted in the breast milk but on the basis of its physico-chemical properties this is considered unlikely. There is no information to suggest that the use of sodium cromoglicate by nursing mothers has any undesirable effects on the baby.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Nausea, vomiting, diarrhoea, abdominal discomfort, skin rashes and joint pains.
Hypersensitivity reactions have been reported extremely rarely.

4.9 Overdose

As Nalcrom is only absorbed to a minimum extent, no action other than medical supervision should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium cromoglicate inhibits the release from mast cells of mediators of the allergic reaction. In gastrointestinal allergy the release of mediators can result in gastrointestinal symptoms or may allow absorption of antigenic material leading to systemic allergic reactions.

5.2 Pharmacokinetic properties

Not applicable.

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

Purified water

Capsule Shell
Gelatin

Printing Ink
Shellac
Ammonium Hydroxide
Potassium Hydroxide
Black Iron Oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package. Keep the bottle tightly closed.

6.5 Nature and contents of container

HDPE bottle with screw cap containing 100 capsules.

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

Italchimici SpA
Via Pontina 5
km 29
00040 Pomezia (Rome)
Italy

8 MARKETING AUTHORISATION NUMBER

PA 1249/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 11 April 2004

10 DATE OF REVISION OF THE TEXT

July 2005