SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Cromoglicate 100mg hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100mg Sodium Cromoglicate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules (capsules)

Transparent capsule with circular double band on body and cap, containing white to off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Posology

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 reduced to the minimum required to maintain the patient free from symptoms.

Method of administration

Sodium Cromoglicate must be administered orally

4.3 Contraindications

Contraindicated in patients with a known hypersensitivity to Sodium Cromoglicate or to any of the excipients.

4.4 Special warnings and precautions for use

None Stated.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, 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 has any undesirable effects on the baby.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Nausea, skin rashes and joint pains have been reported in a few cases.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiallergic agents, excluding corticosteroids, ATC Code: A07EB01

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

Capsule Shell

Gelatin

Printing Ink

Shellac

Propylene Glycol

Black iron Oxide (E172)

Potassium Hydroxide

6.2 Incompatibilities

None Stated

6.3 Shelf life

36 months

After first opening: 1 month

6.4 Special precautions for storage

Keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

White opaque HDPE container with child resistant closure containing 100 capsules.

6.6 Special precautions for disposal

Any unused medicinal product should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Strandhaven Limited t/a Somex Pharma
Ilford
Essex
IG3 8BS.UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 15764/0161

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/03/2016

10 DATE OF REVISION OF THE TEXT

28/06/2022