SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium cromoglicate 100 mg/5 ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml ampoule of oral solution contains 100 mg sodium cromoglicate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

Clear colorless solution. Free from any visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic treatment of allergic symptoms caused by components of the feed, if these components cannot be avoided.

4.2 Posology and method of administration

Posology

The optimal dosage should be determined individually for each patient. The prescribed dose should be taken 15 minutes before the meal. 3 times before the meal and 1 time before bedtime in case of 4x daily dose.

Adults:

Drink the content of 2 ampoules of 5 ml (200 mg) 4 x day.

Paediatric population:

Drink the content of an ampoule of 5 ml (100 mg) 4 x day.

There is insufficient data to assess potential harmfulness about the use of sodium cromoglicate in children below 2 years of age.

If an unsatisfactory result is achieved within 2-3 weeks, the dosage may be increased up to a maximum of 40 mg/kg/day. Try to decrease the dosage, if a satisfactory result has been achieved.

If feed allergy already occurs in the mouth, it is recommended to rinse the mouth with the oral solution prior to swallowing.

Method of administration

Oral use

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Do not use in patients with a medical history of anaphylactic shock or other life-threatening reactions to food.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are no or limited amount of data from the use of sodium cromoglicate in pregnant women.

Animal studies are insufficient with respect to reproductive toxicity and fertility. (see section 5.3)

Sodium cromoglicate is not recommended during first trimester of pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to sodium cromoglicate is presumed negligible. Sodium cromoglicate can be used during breast-feeding.

Fertility

There are no data indicating a harmful effect of sodium cromoglicate on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. An effect is unlikely.

4.8 Undesirable effects

Side effects can occur in the following frequencies: very often (≥ 1/10), often (≥ 1/100, < 1/10), sometimes (≥ 1/1.000, < 1/100), rarely (≥ 1/10.000, < 1/1.000), very rarely (< 1/10.000), not known (cannot be determined by the available data).

Nutrition and metabolic disorders

rarely:

- nausea
- vomit
- diarrhea
- stomach complaints.

Skin and subcutaneous tissue disorders

rarely:

- skin rash.

Skeletal muscle and connective tissue disorders

rarely:

- joint pain.

General diseases and site disorders

very rarely:

- hypersensitivity reactions.

Reporting of suspected adverse effects

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 Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No cases of overdose have been reported

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory drugs; Anti-allergic agents, excluding corticosteroids; ATC-code: A07EB01.

Sodium cromoglicate exerts a stabilizing effect on mast cells, from which transfer agents ("mediators") are released. Mediator release causes local inflammation in gastrointestinal disorders, which causes gastrointestinal symptoms or allows absorption of substances containing antigen leading to systemic and local allergic reactions.

5.2 Pharmacokinetic properties

Absorption after oral dosage is low (< 1 %).

5.3 Preclinical safety data

No details are known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 year

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Sodium cromoglicate oral solution is available in 5 ml ampoule of LDPE Blow fill seal (BFS) container with twist off cap.

Pack sizes: 8, 96 ampoules

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0146

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/05/2018
Renewal of the authorisation: 13/04/2023

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14/07/2023