

New Zealand Data Sheet

1. PRODUCT NAME

Nalcrom® 100mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Nalcrom 100mg capsule contains 100 mg of sodium cromoglicate.

Excipient(s) with known effect

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

It is presented in clear/clear hard gelatin capsules, size No. 2, overprinted with SODIUM CROMOGLICATE 100 mg in black and containing a white powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For chronic inflammatory conditions such as proctitis, ulcerative colitis and proctocolitis, and for use in the treatment of food allergic disease.

4.2. Dose and method of administration

Dose

Initial dosage

Adults

2 capsules four times daily.

Children (2-14 years)

1 capsule four times daily.

Nalcrom should not be used in children under 2 years. to recommend not to prematurely discontinue a treatment in case of specific non-serious adverse reaction(s) that are frequent but transient or manageable with dose titration.

Maintenance dosage

Adults and Children

Once symptoms are controlled, the dose may be reduced to the lowest necessary to maintain freedom from symptoms.

Patients currently treated with other formulations of sodium cromoglicate should continue with their normal dosage.

Method of Administration

Nalcrom is a presentation of sodium cromoglicate for oral use. The capsules maybe swallowed whole or the powder contents maybe dissolved in a small quantity of very hot water and diluted with cold water to drink. Administration as a solution in water is probably the method of choice.

4.3. Contraindications

Nalcrom is contraindicated in patients with known hypersensitivity to sodium cromoglicate or any of the other constituents.

4.4. Special warnings and precautions for use

None stated.

4.5. Interaction with other medicines and other forms of interaction

Sodium cromoglicate has been used for the treatment of a variety of indications in man and it has been the subject of drug interaction studies in animals. No harmful interactions with other drugs are known.

4.6. Fertility, pregnancy and lactation

Pregnancy

Category A

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

Lactation

On the basis of animal studies and its physicochemical properties, sodium cromoglicate is considered unlikely to pass into human breast milk. There is no information to suggest the use of sodium cromoglicate by nursing mothers has any undesirable effects on the baby.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

In topical use in the lung and nose, sodium cromoglicate has shown a very high margin of safety. Occasional reports of nausea, skin rashes and joint pain.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9. Overdose

As Nalcrom is absorbed only to a very limited extent, no action other than medical observation should be necessary.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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

Action

Sodium cromoglicate is considered to exert a stabilising effect upon mast cells capable of releasing mediators thus preventing the local inflammatory reaction in the gastrointestinal tract. In the case of food allergic disease, sodium cromoglicate is capable of reducing or preventing the absorption of antigen, the formation of immune complexes and the clinical signs and symptoms consequent upon ingestion of the antigen. In addition, the site of action is local, probably by stabilisation of the mast cell membranes, preventing the local inflammatory reaction in the gastro-intestinal tract, as well as secondary reaction in other organs which may be caused by leakage of antigenic materials into the general circulation.

5.2. Pharmacokinetic properties

Sodium cromoglicate is poorly absorbed from the gastro-intestinal tract when given orally. About 1% of an oral dose is absorbed. Excretion is via biliary and renal routes as the unchanged substance. Plasma half-life is about 80 minutes.

5.3. Preclinical safety data

Refer to section 4.6.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Gelatin capsule, black ink.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

48 months.

6.4. Special precautions for storage

Store at or below 30°C. Reclose the container tightly after use.

6.5. Nature and contents of container

Plastic bottle, 100 capsules.

6.6. Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription medicine

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

20 November 1977

10.DATE OF REVISION OF THE TEXT

01 February 2019

Summary table of changes

Section Changed	Summary of new information
All	SPC format