

NALCROM

Sodium cromoglicate, 100 mg capsules

Presentation

NALCROM is a presentation of sodium cromoglicate for oral use. It is presented in clear/clear hard gelatin capsules, size No. 2, overprinted with SODIUM CROMOGLICATE 100 mg in black. Each capsule contains 100 mg sodium cromoglicate as a white powder.

Uses

Actions

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.

Pharmacokinetics

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.

Indications

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

Dosage and Administration

The capsules may be swallowed whole or the powder contents may be 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.

Initial Dosage:

Adults

Two capsules four times daily.

Children (2-14 years)

One capsule four times daily.

NALCROM should not be used in children under 2 years.

Maintenance Dosage:**Adults and Children**

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

Contraindications

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

Warnings And Precautions***Pregnancy*****Category A**

Cumulative experience with sodium cromoglicate suggest 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.

Adverse 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.

Interactions

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.

Overdosage

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

Pharmaceutical Precautions

Store in a dry place, below 30°C. Reclose the container tightly after use.

Medicine Classification

Prescription Medicine

Package Quantities

Container of 100 capsules.

Further Information

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

Name and Address

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