

INTAL SPINCAPS

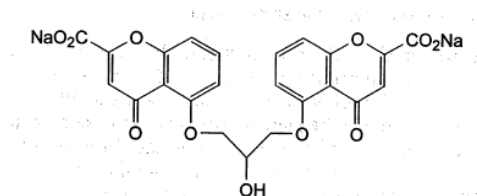
Sodium Cromoglicate 20 mg Capsules

Name of the Medicine

INTAL SPINCAPS
Sodium Cromoglicate 20 mg capsules.

Description

Sodium cromoglicate is a white or almost white, crystalline powder. The chemical name of sodium cromoglicate is disodium 5,5'-[(2-hydroxypropane-1,3-diyl)bis(oxy)]bis(4-oxo-4H-1-benzopyran-2-carboxylate). The molecular formula of sodium cromoglicate is $C_{23}H_{14}N_2O_{11}$ and the molecular weight is 512.3. The structural formula is:



INTAL SPINCAPS are micronised sodium cromoglicate in a yellow/colourless gelatin capsule, overprinted with “SODIUM CROMOGLICATE 20 mg” for use with the SPINHALER inhalation device.

Pharmacology

Mechanism of Action

Sodium cromoglicate is a derivative of chromone-2-carboxylic acid, which inhibits the activation of many of the cell types involved in the development and progression of asthma. Thus, sodium cromoglicate prevents the formation of IgE antibody or B lymphocytes, inhibits the release of inflammatory mediators including cytokines from mast cells and reduces the chemotactic activity of eosinophils and neutrophils. Activation and mediator release from monocytes and macrophages is also reduced with sodium cromoglicate.

Sodium cromoglicate inhibits antigen-induced early and late phase airway obstruction in conscious animals and reduces the influx of inflammatory cells into the airways. The drug also inhibits sensory nerve (C fibre) activation in the dog lung and inflammatory responses in the airways of animals induced by neuronal stimulation.

This diverse range of activities of the drug may be explained by the ability of sodium cromoglicate to block chloride channels in different cell types that are important in cell activation.

In acute bronchial provocation tests sodium cromoglicate has been shown to inhibit or diminish the asthmatic reaction to antigen, exercise and to a range of non-specific triggers including cold air, sulphur dioxide, hypertonic saline and bradykinin. Antigen-induced increased bronchial hyperreactivity to histamine is prevented and a reduction in bronchial mucus eosinophils and antigen-specific IgE occurs after 4 weeks with treatment of asthmatic subjects with sodium cromoglicate.

Pharmacokinetics

After inhalation as a dry powder via a Spinhaler between 5-15 % of a dose of sodium cromoglicate is absorbed from the respiratory tract. The amount depends on the inspiratory flow rate. The remainder is either exhaled or deposited in the oropharynx, swallowed and eliminated via the alimentary tract, as only a small amount (1 %) of the dose is absorbed from the gut.

Indications

INTAL SPINCAPS are indicated for the preventative treatment of bronchial asthma (which may be due to allergy, exercise, cold air or chemical irritants), in adults and children.

Contraindications

Known hypersensitivity to sodium cromoglicate.

Precautions

General

INTAL SPINCAPS must not be used for relief of an acute attack of bronchospasm. Since the therapy is prophylactic it is important to continue treatment in those patients who benefit. If it is necessary to withdraw this treatment, it should normally be done progressively over a period of one week. Symptoms of asthma may recur.

Use in 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 great need.

Use in Lactation

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

Effects on Ability to Drive or Operate Machinery

Sodium cromoglicate has no known effect on the ability to drive or operate machinery.

Interactions with other Medicines

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

Adverse effects

Mild throat irritation, coughing and transient bronchospasm may occur. As with other inhalation therapy, paradoxical bronchospasm may occur immediately after administration; in such cases the product should be discontinued and alternate treatment instituted. Hypersensitivity reactions, including angioedema, bronchospasm, hypotension and collapse, have been reported extremely rarely.

Dosage and Administration

The recommended dosage is one capsule four times daily. The suggested dosage regime is one capsule night and morning and at regular intervals of 3-6 hours during the day. The dose may be increased to one capsule 6-8 times daily in more severe cases or during periods of high antigen challenge.

When the asthmatic condition is stabilized it is sometimes possible to reduce the dosage, but this must be carefully assessed for each individual patient, to ensure adequate control of asthma. In patients currently treated with oral or inhaled steroids, the addition of sodium cromoglicate may allow reduction or discontinuation of the steroid dose. The patient must be carefully supervised while the steroid dose is reduced in a step-wise fashion. If possible peak flow monitoring should be continued during such reductions and patients given instructions about what action to take if deterioration occurs.

For protection against bronchospasm induced by exercise INTAL SPINCAPS should be used 15-30 minutes beforehand.

INTAL SPINCAPS must be administered via a Spinhaler. The capsules are not effective if swallowed. INTAL SPINCAPS therapy is preventative and it is therefore important to instruct the patient to maintain regular dosing, as distinct from inhaling the drug as needed to relieve symptoms.

As several doses may be needed to establish benefit, relief may not be apparent immediately but may take some weeks to develop.

Overdosage

Animal studies have shown that sodium cromoglicate has a very low order of local or systemic toxicity and extended human studies have not revealed any safety hazard with the product. Overdosage is therefore unlikely to cause problems but if suspected, treatment should be supportive and directed to the control of relevant symptoms.

Presentation and Storage conditions

Storage

Store below 30 °C. Shelf life is 3 years.

Pack quantities

INTAL SPINCAPS are available as 50's Spinhaler: PVC blister with aluminum foil backing enclosed in a sachet, containing 10 capsules.

Medicine Classification

Prescription Medicine.

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