



Nacromin[®] Cozycap

Sodium cromoglycate

Non steroidal, Antiasthmatic, Antiallergic inhalant

COMPOSITION

Nacromin[®] Cozycap : Each Nacromin[®] Cozycap contains Sodium cromoglycate BP 20 mg.

PHARMACOLOGY

Nacromin[®] (Sodium cromoglycate) is an antiasthmatic, antiallergic and mast cell stabilizer. It has no intrinsic bronchodilator, antihistaminic, vasoconstrictor or anti-inflammatory activity. It prevents release of the mediators of type I allergic reactions, including histamine and slow reacting substance of anaphylaxis (SRS-A) from sensitized mast cells after the antigen-antibody union has taken place. The drug does not inhibit the binding of IgE to mast cells nor the interaction between cell bound IgE and the specific antigen; instead, sodium cromoglycate suppresses the release of substances (e.g; histamin, SRS-A) in response to this reaction. The drug also inhibits type III (late allergic, arthus) reactions to a lesser extent. The action of sodium cromoglycate on the mast cell is not restricted to antigen-evoked secretion, since the drug has also been shown to inhibit secretion induced by other mast cell secretagogues (e.g; the polyamine 48/80). Bronchial asthma induced by the inhalation of antigens can be inhibited to varying degrees by sodium cromoglycate pre-treatment.

Sodium cromoglycate acts locally on the lungs to which it is directly applied. The inhalation capsule delivers more drugs to the lungs compared to nebulization of solution, but there is no difference in effectiveness.

INDICATION

Nacromin[®] Cozycap for inhalation is indicated for the preventive treatment of mild to moderate bronchial asthma, including the prevention of exercise-induced asthma.

Sodium cromoglycate can prevent the asthmatic response to a variety of allergic and non-allergic stimuli. It is used in the management of chronic asthma for patients who cannot be managed with inhaled β_2 -agonists alone; it is not used for acute attacks including acute severe asthma (*status asthmaticus*).

It is important that the regular administration of sodium cromoglycate is maintained both in the prophylactic control of asthma and in the management of other allergic conditions. Beneficial effects may take several weeks to become established.

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DOSAGE AND ADMINISTRATION

Adults and Children over 5 years of age

It should be administered by the orally inhaled route with Cozyhaler device. Usual dose for adult and Children over 5 years of age is 20 mg i.e. 01 Nacromin® Cozycap, 4 times daily, increased in severe cases to 8 times daily; additional doses may also be taken before exercise. Once the asthma has been stabilized it may be possible to reduce the dosage.

CONTRAINDICATION AND PRECAUTION

Nacromin® Cozycap is contraindicated in those patients who have shown hypersensitivity to Sodium cromoglycate or to any of its components. It is not indicated as the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

The recommended dosage should be decreased in patients with renal or hepatic dysfunction.

Concomitant bronchodilator therapy: Where a concomitant bronchodilator is prescribed, it is recommended that this be administered prior to the sodium cromoglycate dry powder inhalation.

Concomitant steroid therapy: In patients currently treated with steroids the addition of sodium cromoglycate dry powder inhalation to the regimen may make it possible to reduce the maintenance dose or to discontinue steroid completely. The patient must be carefully supervised while the steroid dose is reduced; a rate of reduction of 10% weekly is suggested. If reduction of steroid dosage is possible, sodium cromoglycate dry powder inhalation should not be withdrawn until steroid cover has been re-instituted.

Since the therapy is prophylactic, it is important to continue therapy in those patients who get benefit. If it is necessary to withdraw this treatment, it should be done progressively over a period of one week.

SIDE EFFECT

Sodium cromoglycate is well-tolerated, mild throat irritation, coughing and transient bronchospasm may occur. Very rarely, severe bronchospasm associated with a marked fall in pulmonary functions has been reported. In such cases, treatment should be stopped and should not be re-introduced. Reactions sometimes occurring after several months of treatment include aggravation of existing asthma, urticaria, rashes and pulmonary infiltration with eosinophilia.

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USE IN PREGNANCY AND LACTATION

As with all medication, caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with sodium cromoglycate 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 cromoglycate is excreted in the breast milk but on the basis of its physico-chemical properties this is considered unlikely. There is no evidence to suggest that the use of sodium cromoglycate has any undesirable effects on the breast-fed baby.

STORAGE CONDITION

- Store in a cool place away from heat & moisture.
- Keep the container tightly closed.
- Insert the COZYCAP in the COZYHALER just prior to use, as COZYCAP exposed to moisture may not break open easily

HOW SUPPLIED

Nacromin[®] Cozycap : Box containing 30 capsules in moisture proof container.

