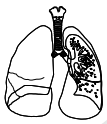

Nacromin®

Sodium Cromoglycate

Topical Anti-Allergic

COMPOSITION

Nacromin® 2% Nasal Drops : Each ml contains 20 mg Sodium Cromoglycate BP.

PHARMACOLOGY

Nacromin® appears to act mainly through a local effect on the nasal mucosa. Less than 7% of an intranasal dose of Nacromin® is absorbed systemically. Nacromin® 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 and the specific antigen; instead Nacromin® suppress the release of substances (e.g. histamine, SRS-A) in response to this reaction. The drug also inhibits Type-III (late allergic, Arthers) reactions to a lesser extent.

INDICATION

Nacromin® 2% Nasal Drops is used for the symptomatic prevention and treatment of seasonal or perennial allergic rhinitis. Intranasal administration of Nacromin® 2% Nasal Drops generally provides symptomatic relief of rhinorrhea, nasal congestion, sneezing and postnasal drip.

DOSAGE AND ADMINISTRATION

Adults (including the elderly) and children: Initial two drops into each nostril four to six times daily or as directed by the physician.

For optimum symptomatic relief in patients with perennial allergic rhinitis, up to 2-4 weeks of therapy with Nacromin® 2% Nasal Drops may be required. It is important that the patient should be instructed to maintain regular dosage.

Prophylactic treatment for seasonal allergic rhinitis should begin at least one week before exposure to the offending allergen and should continue throughout the season.

CONTRAINDICATION AND PRECAUTION

Nacromin® 2% Nasal Drops is contraindicated in individuals who have shown hypersensitivity to the drug or any ingredient of the preparation. Use of Nacromin® 2% Nasal Drops is not recommended in children younger than 6 years of age.

SIDE EFFECT

Occasional irritation of nasal mucosa may occur during the first days of use. In rare cases wheezing or tightness of the chest have been reported.

DRUG INTERACTION

There is no significant interaction with other anti-allergic agents such as antihistamines, decongestants, corticosteroids etc. and those agents can be used concomitantly.

USE IN PREGNANCY AND LACTATION

In animal studies, Sodium Cromoglycate has produced adverse effects on the fetus only in high parenteral doses. There was no evidence of impaired fertility in reproduction studies in animals. Healthy infants have been born to women who received Sodium Cromoglycate throughout pregnancy. Nevertheless, there is insufficient evidence to establish the safety in pregnancy. It should be used during pregnancy only when clearly needed. Since it is not known if Sodium Cromoglycate is distributed into milk in humans, the drug should be used with caution in nursing women.

STORAGE CONDITION

Nacromin® 2% Nasal Drops should be protected from direct sunlight and stored at a temperature less than 30˚C; any unused Nacromin® 2% Nasal Drops should be discarded 4 weeks after breaking the seal of the cap of the bottle.

HOW SUPPLIED

Nacromin® 2% Nasal Drops : 15 ml nasal drops in plastic droppered bottle.