



# Nacromin<sup>®</sup> Eye Drops

Sodium Cromoglycate  
**Anti Allergic**

## COMPOSITION

Nacromin<sup>®</sup> 2% Eye Drops : Each ml sterile solution contains 20 mg Sodium Cromoglycate BP.

## PHARMACOLOGY

Nacromin<sup>®</sup> 2% sterile Eye Drops inhibits the release of chemical mediators from sensitised mast cells and is capable of rapid phosphorylation of mast cell protein. The exact mechanism of action of the drug remains to be elucidated but Sodium Cromoglycate appears to modulate the allergic response to antigen antibody interactions in a way which prevents the subsequent formation or release of toxic or inflammatory mediators. Nacromin<sup>®</sup> 2% Eye Drops appears to act mainly through a local effect on the mucous of the eye. Approximately 0.03% of an ophthalmic dose of Nacromin<sup>®</sup> 2% Eye Drops is absorbed systemically. Nacromin<sup>®</sup> 2% Eye Drops prevent, release of mediators of type-I allergic reactions, including histamine and slow reacting substance of anaphylaxis (SRS-A) from sensitised 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. histamine, SRS-A) in response to this reaction. The drug also inhibits Type-III (late allergic, Arthus) reactions.

## INDICATION

Nacromin<sup>®</sup> 2% Eye Drops is used for the prophylaxis and symptomatic treatment of certain allergic ocular disorders including vernal kerato conjunctivitis, vernal conjunctivitis, giant papillary conjunctivitis, vernal keratitis and allergic keratoconjunctivitis.

Ophthalmic administration of Nacromin<sup>®</sup> 2% Eye Drops generally provides symptomatic relief of itching, tearing, redness and discharge within a few days following initiation of therapy; however, up to 6 weeks of therapy may be required for optimum symptomatic relief in some patients.

Once symptomatic improvement has been established therapy should be continued for as long as needed to sustain improvement.

## DOSAGE AND ADMINISTRATION

The usual dosage of Nacromin<sup>®</sup> 2% Eye Drops in adults and children over 4 years of age or older is 1 or 2 drops in each eye 4-6 times daily at

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regular intervals. The recommended frequency of administration should not be exceeded.

Patients should be advised that the therapeutic effects of Nacromin<sup>®</sup> 2% Eye Drops depend on administration of the drug at regular intervals.

### **CONTRAINDICATION AND PRECAUTION**

Sodium Cromoglycate 2% Eye Drops is contraindicated in individuals who have shown hypersensitivity to the drug or any of the ingredients.

Sodium Cromoglycate 2% Eye Drops contains benzalkonium chloride and patients should be advised not to wear soft contact lenses during treatment with Sodium Cromoglycate 2% Eye Drops.

### **SIDE EFFECT**

The most frequent adverse effect reported with use of Sodium Cromoglycate 2% Eye Drops is transient ocular stinging or burning upon instillation of the drug.

### **DRUG INTERACTION**

Sodium Cromoglycate has no known drug interactions.

### **USE IN PREGNANCY AND LACTATION**

In animal studies, Sodium Cromoglycate has produced adverse effects on the foetus 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**

Sodium Cromoglycate 2% Eye Drops should be protected from direct sunlight and stored at a temperature less than 30°C; any unused ophthalmic solution should be discarded 4 weeks after opening the cap of the bottle.

### **HOW SUPPLIED**

Nacromin<sup>®</sup> 2% Eye Drops : Dropper bottle containing 10 ml of sterile solution.

