METACROM NASAL SPRAY

(Sodium Cromoglycate 4% w/v)

COMPOSITION

Each mL contains Sodium Cromoglycate 40 mg (4% w/v). Other ingredients: as per the approved formulation.

DESCRIPTION

Metacrom is a nasal preparation containing sodium cromoglycate (also called sodium cromoglicate), an anti-allergic mast-cell stabiliser for topical intranasal administration.

CLINICAL PHARMACOLOGY

Sodium cromoglycate stabilises sensitised mast cells and inhibits release of mediators involved in allergic reactions. It helps prevent nasal allergic symptoms rather than providing rapid relief of an acute attack. Following intranasal use, only a small proportion of the dose is absorbed systemically; absorbed drug is excreted largely unchanged.

INDICATIONS

Preventive treatment of seasonal allergic rhinitis (hay fever) and perennial allergic rhinitis.

DOSAGE AND ADMINISTRATION

Adults and children: One spray into each nostril two to four times daily, or as prescribed. Regular use is important, including on symptom-free days during allergen exposure. Do not exceed the prescribed dose. This product is not intended for immediate relief of severe acute allergic symptoms.

DIRECTIONS FOR USE

For nasal use only. Blow the nose gently. Remove the cap; prime the pump before first use as directed by the approved device instructions. Keeping the head upright, insert the nozzle into one nostril, close the other nostril and press the pump while breathing in gently. Repeat for the other nostril. Wipe the nozzle and replace the cap. Avoid sharing the bottle.

CONTRAINDICATIONS

Known hypersensitivity to sodium cromoglycate or any ingredient of the formulation.

WARNINGS AND PRECAUTIONS

For intranasal administration only; do not swallow or spray into the eyes. Regular prophylactic administration is needed for full benefit. Consult a healthcare professional if symptoms persist, worsen, or are accompanied by significant nasal bleeding or breathing difficulty. Avoid contact of the nozzle with unclean surfaces. If an allergic reaction occurs, stop use and seek medical advice.

DRUG INTERACTIONS

No clinically important interactions are known for intranasal sodium cromoglycate. Tell your healthcare professional about all medicines being used, including other nasal preparations.

PREGNANCY

Available clinical experience has not indicated an adverse effect on fetal development; nevertheless, use during pregnancy only when there is a clear clinical need and on medical advice.

LACTATION

Transfer into breast milk is considered unlikely because systemic exposure is low. There is no evidence suggesting harm to breastfed infants, but the need for treatment should be assessed by a healthcare professional.

PEDIATRIC USE

The reference 4% nasal spray prescribing information includes use in children. Children should use the product with adult supervision and according to a clinician's directions and the approved local label.

GERIATRIC USE

No separate dose adjustment is established in the reference information. Follow individual clinical advice.

EFFECT ON DRIVING AND MACHINERY

No significant effect on the ability to drive or use machinery is expected. If a patient experiences headache or other troublesome symptoms, use caution.

ADVERSE REACTIONS

Occasional nasal irritation, burning or stinging, sneezing, unpleasant taste, headache and nausea may occur. Rarely, wheezing or chest tightness has been reported. Seek immediate medical assistance for severe breathing difficulty, facial swelling or other signs of a serious hypersensitivity reaction.

OVERDOSAGE

Sodium cromoglycate has low systemic toxicity after intranasal use. In case of substantial accidental ingestion or unexpected symptoms, seek medical advice. Management is usually observation and supportive treatment as clinically indicated.

PHARMACEUTICAL PRECAUTIONS

Do not use if tamper evidence is broken, the spray mechanism is damaged, or solution appearance has changed. Keep the nozzle clean. Do not transfer the contents to another container.

STORAGE CONDITIONS

Store according to the approved product label, protected from excessive heat and direct sunlight. Keep the bottle closed when not in use. Follow the product-specific in-use period after opening. Keep out of reach of children.

PRESENTATION

METACROM NASAL SPRAY: Sodium Cromoglycate 4% w/v (40 mg/mL), supplied in a 15 mL nasal spray bottle.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.