# VEGASONE NASAL SPRAY

Mometasone Furoate 50 micrograms per metered spray.
**Pack: 120 metered sprays | For intranasal use only.**

## COMPOSITION

Each metered actuation delivers mometasone furoate equivalent to **50 micrograms**. The precise hydrate/salt equivalence and excipients are as specified in the approved Vegasone formulation.

## THERAPEUTIC CLASS

Intranasal corticosteroid (glucocorticoid); anti-inflammatory and anti-allergic agent. Medical segments: ENT, Allergy and General Practice.

## PHARMACOLOGY

Mometasone furoate is a locally acting corticosteroid with anti-inflammatory effects. It reduces nasal mucosal inflammation and symptoms such as sneezing, itching, rhinorrhoea and congestion. Systemic exposure is generally low at recommended intranasal doses.

## INDICATIONS

Depending on the locally approved product information: treatment of seasonal or perennial allergic rhinitis in adults and children; prevention of seasonal allergic rhinitis in eligible patients; and treatment of nasal polyps in adults. Not intended for immediate relief of acute severe symptoms.

## DOSAGE: ALLERGIC RHINITIS

**Adults and adolescents aged 12 years and older:** 2 sprays in each nostril once daily (200 micrograms/day). When symptoms are controlled, the prescriber may reduce to 1 spray in each nostril once daily. **Children 2–11 years:** 1 spray in each nostril once daily (100 micrograms/day), only where approved and with adult assistance. Follow local age restrictions.

## DOSAGE: NASAL POLYPS

**Adults aged 18 years and older:** 2 sprays in each nostril twice daily (400 micrograms/day), or once daily (200 micrograms/day) in selected patients according to response and approved labeling. Do not use in children for this indication unless specifically authorized.

## PREVENTION OF SEASONAL ALLERGIC RHINITIS

Where approved, adults and adolescents 12 years and older may use 2 sprays in each nostril once daily, beginning approximately 2–4 weeks before anticipated allergen exposure.

## PREPARATION AND PRIMING

Shake well before each use. Before first use, prime the pump with approximately 10 actuations or until a uniform fine spray appears. If unused for more than 1 week, reprime with approximately 2 actuations or until a fine spray appears. Confirm priming requirements for the actual Vegasone pump.

## INSTRUCTIONS FOR USE

Gently blow the nose. Shake bottle; remove cap. Tilt head slightly forward. Close one nostril and insert nozzle into the other, pointing away from the nasal septum. Breathe in gently while pressing the pump once; breathe out through the mouth. Repeat as prescribed. Wipe nozzle and replace cap. Do not share the bottle.

## CONTRAINDICATIONS

Known hypersensitivity to mometasone furoate or any ingredient. Check the approved formulation for other product-specific contraindications.

## WARNINGS: LOCAL NASAL EFFECTS

Nosebleeds, nasal ulceration, Candida infection and, rarely, nasal septal perforation may occur. Avoid spraying directly onto the septum. Examine patients periodically during prolonged use. Avoid use on unhealed nasal wounds following surgery or trauma until healing has occurred.

## WARNINGS: INFECTION AND SYSTEMIC EFFECTS

Corticosteroids may worsen untreated local infections and increase susceptibility to certain infections. Use caution in patients with tuberculosis or untreated fungal, bacterial or viral infections. Rare systemic corticosteroid effects include adrenal suppression, glaucoma, cataracts and growth effects in children; use the lowest effective dose.

## PRECAUTIONS

Monitor children receiving prolonged therapy for growth. Evaluate persistent visual changes, recurrent nosebleeds, nasal irritation or signs of infection. Symptom relief may require regular daily use; do not exceed the prescribed dose.

## DRUG INTERACTIONS

Strong CYP3A4 inhibitors (such as ritonavir or cobicistat-containing regimens and some azole antifungals) may increase systemic corticosteroid exposure. Assess concomitant corticosteroid therapy and other medicines.

## PREGNANCY AND LACTATION

Use during pregnancy or breastfeeding only after the prescriber weighs expected benefits against potential risks. Use the lowest effective dose when treatment is necessary.

## ADVERSE REACTIONS

Headache, epistaxis, nasal irritation or burning, sneezing, sore throat and upper respiratory symptoms may occur. Rare serious reactions include severe hypersensitivity, visual disturbances and systemic corticosteroid effects.

## OVERDOSAGE

Excessive or prolonged dosing may increase systemic corticosteroid effects. Seek medical advice if substantial overdose or repeated excessive use is suspected; management is supportive.

## STORAGE AND HANDLING

Store as stated on the approved Vegasone label; protect from excessive heat and light. Do not freeze. Keep the cap in place and out of reach of children. Follow the validated in-use shelf life and the labelled number of metered sprays.

## PRESENTATION

Vegasone Nasal Spray, 50 micrograms per metered spray; bottle providing **120 metered sprays**.

## MANUFACTURED BY

**Vega Pharmaceuticals (Pvt.) Ltd.**