

PRESCRIBING INFORMATION

Metaspray[®]

Mometasone Furoate 50 mcg/spray

COMPOSITION

Metaspray[®] Nasal Spray: Each spray contains 50 mcg Mometasone Furoate BP.

PHARMACOLOGY

Mometasone Furoate monohydrate is a corticosteroid demonstrating anti-inflammatory properties. The precise mechanism of corticosteroid action on allergic rhinitis is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (eg, histamines, eicosanoids, leukotrienes, and cytokines) involved in inflammation. Protein binding for Mometasone Furoate was reported to be 98% to 99% in concentration range of 5 to 500 ng/mL. The effective plasma elimination half-life of Mometasone Furoate is 5.8 hours.

INDICATIONS

Metaspray[®] Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older. It is indicated for the prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years and older. It is also indicated for the treatment of nasal polyps in patients 18 years and older.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of this preparation contraindicates its use.

DOSAGE AND ADMINISTRATION

Allergic Rhinitis

Adults and Children 12 Years of Age and Older: The recommended dose for prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis and treatment of the nasal symptoms of perennial allergic rhinitis is two sprays (50 mcg of Mometasone Furoate in each spray) in each nostril once daily (total daily dose of 100 mcg). In patients with a known seasonal allergen that precipitates nasal symptoms of seasonal allergic rhinitis, prophylaxis with **Metaspray[®]** Nasal Spray, 50 mcg (200 mcg/day) is recommended 2 to 4 weeks prior to the anticipated start of the pollen season.

Children 2 to 11 Years of Age: The recommended dose for treatment of the nasal symptoms of

seasonal and perennial allergic rhinitis is one spray (50 mcg of Mometasone Furoate in each spray) in each nostril once daily (total daily dose of 100 mcg).

Nasal Polyps

Adults 18 years of Age and Older: The recommended dose for nasal polyps is two sprays (50 mcg of Mometasone Furoate in each spray) in each nostril twice daily (total daily dose of 400 mcg). A dose of two sprays (50 mcg of mometasone furoate in each spray) in each nostril once daily (total daily dose of 200 mcg) is also effective in some patients.

PRECAUTIONS

While using nasal corticosteroids, caution is required in patients with active or dormant tuberculous infection, or in untreated fungal, bacterial, systemic viral infections, or ocular herpes simplex.

SIDE EFFECTS

Side effects are generally mild and included headache, viral infection, sore throat, nosebleeds, and coughing.

SPECIAL POPULATION

Use in Pregnancy

There are no adequate and well-controlled studies in pregnant women. Mometasone Furoate, like other corticosteroids, should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

Nursing Mothers

It is not known if Mometasone Furoate is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be used when Mometasone is administered to nursing women.

OVERDOSE

There are no data available on the effects of acute or chronic overdosage with Mometasone. Because of low systemic bioavailability, and an absence of acute drug-related systemic findings in clinical studies, overdose is unlikely to require any therapy other than observation.

STORAGE

Store below 30° C. Protect from light. Keep all medicines out of the reach of children.

HOW SUPPLIED

Metaspray[®] Nasal Spray: Each bottle contains Mometasone Furoate aqueous suspension adequate for 120 metered sprays.

Manufactured by:



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