

NEW ZEALAND DATA SHEET

NASONEX AQUEOUS NASAL SPRAY

NAME OF MEDICINE

NASONEX AQUEOUS NASAL SPRAY
Mometasone furoate monohydrate

PRESENTATION

Nasonex Aqueous Nasal Spray is a metered-dose, manual pump spray unit containing a suspension of mometasone furoate. Each actuation delivers approximately 100mg of mometasone furoate monohydrate suspension, containing mometasone furoate monohydrate equivalent to mometasone furoate 50µg.

USES

Actions

Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

Clinical Pharmacology/Pharmacokinetics

Mometasone furoate, administered as a nasal spray, has negligible ($\leq 0.1\%$) systemic bioavailability and is generally undetectable in plasma, despite the use of a sensitive assay with a lower quantitation limit of 50pg/mL; thus there are no relevant pharmacokinetic data for this dosage form. Mometasone furoate suspension is very poorly absorbed from the gastrointestinal tract, and the small amount that may be swallowed and absorbed undergoes extensive first-pass metabolism prior to excretion in urine and bile.

In studies utilising nasal antigen challenge, Nasonex Aqueous Nasal Spray has shown anti-inflammatory activity in both the early- and late-phase allergic responses. This has been demonstrated by decreases (vs placebo) in histamine and eosinophil activity and reductions (vs baseline) in eosinophils, neutrophils and epithelial cell adhesion proteins.

Indications

Nasonex Aqueous Nasal Spray is indicated for the treatment of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis and the prophylaxis of seasonal allergic rhinitis in adults, adolescents and children between the ages of 3 and 11 years.

Nasonex Aqueous Nasal Spray is also indicated for use in adults and adolescents 12 years of age and older as adjunctive treatment to antibiotics for acute episodes of sinusitis.

DOSAGE AND ADMINISTRATION

DO NOT EXCEED THE RECOMMENDED DOSAGE.

Seasonal Allergic Rhinitis or Perennial Allergic Rhinitis

The effect of Nasonex Aqueous Nasal Spray is not immediate. Full therapeutic benefit takes a few days to develop. Dosage should be administered as directed and not be taken by the patients at will for symptomatic relief.

In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with Nasonex is recommended two to four weeks prior to the anticipated start of the pollen season.

Clinically significant onset of action occurs as early as 12 hours after the first dose.

Adults (including geriatric patients) and children 12 years of age and over

The usual recommended dose for prophylaxis and treatment is two sprays (50µg/spray) in each nostril once daily (total daily dose of 200µg). Once symptoms are controlled, reducing the dose to one spray in each nostril (total daily dose of 100µg) may be effective for maintenance.

If symptoms are inadequately controlled, the dose may be increased to four sprays in each nostril (total daily dose of 400µg). Dose reduction is recommended following the control of symptoms.

Children between the ages of 3 and 11 years

The usual recommended dose is one spray (50µg/spray) in each nostril once daily (total daily dose 100µg).

Adjunctive Treatment of Acute Episodes of Sinusitis

Adults (including geriatric patients) and children 12 years of age and over: The usual recommended dose is two sprays (50µg/spray) in each nostril twice daily (total daily dose 400µg).

If symptoms are inadequately controlled, the dose may be increased to four sprays (50µg/spray) in each nostril twice daily (total daily dose 800µg).

Instructions to patients: Shake container well before each use. After the initial priming of the Nasonex Aqueous Nasal Spray pump (usually 6 or 7 actuations, until a uniform spray is observed), each actuation delivers approximately 100mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50µg of mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed before the next use.

CONTRAINDICATIONS

- Patients with known hypersensitivity to mometasone furoate or any of the excipients
- Severe nasal infection, especially candidiasis
- Persons with haemorrhagic diathesis or with a history of recurrent nasal bleeding

WARNINGS AND PRECAUTIONS

Nasonex Aqueous Nasal Spray should not be used in the presence of untreated localised infection involving the nasal mucosa.

Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

Following 12 months of treatment with Nasonex Aqueous Nasal Spray, there was no evidence of atrophy of the nasal mucosa. Mometasone furoate tended to reverse the nasal mucosa closer to a normal histological phenotype. As with any long-term treatment, patients using Nasonex Aqueous Nasal Spray over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localised fungal infection of the nose or pharynx develops, discontinuance of Nasonex Aqueous Nasal Spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing Nasonex Aqueous Nasal Spray.

Nasonex Aqueous Nasal Spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

There is no evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression following prolonged treatment with Nasonex Aqueous Nasal Spray. However, patients who are transferred from long-term administration of systemically active corticosteroids to Nasonex Aqueous Nasal Spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted.

During transfer from systemic corticosteroids to Nasonex Aqueous Nasal Spray, some patients may experience symptoms of withdrawal from systemically active corticosteroids (eg joint and/or muscular pain, lassitude and depression initially) despite relief from nasal symptoms and will require encouragement to continue Nasonex Aqueous Nasal Spray therapy. Such transfer may also unmask pre-existing allergic conditions such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (eg chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Following the use of intranasal aerosolised corticosteroids, instances of nasal septum perforation or increased intraocular pressure have been reported very rarely.

Use in Pregnancy (Category B3) and Use in Lactation

There are no adequate or well controlled studies in pregnant women. Following intranasal administration of the maximum recommended clinical dose to patients, the plasma concentrations of mometasone furoate are not measurable; thus foetal exposure is expected to be negligible and the potential for reproductive toxicity is very low.

As with other nasal corticosteroid preparations, Nasonex Aqueous Nasal Spray should be used in pregnant women or nursing mothers only if the potential benefit justifies the potential risk to the mother, foetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Use in Children

In a placebo-controlled clinical trial in which paediatric patients were administered Nasonex 100µg daily for one year, no reduction in growth velocity was observed.

ADVERSE EFFECTS

Seasonal Allergic Rhinitis or Perennial Allergic Rhinitis

Treatment-related local adverse events reported in clinical studies include headache (8%), epistaxis i.e. frank bleeding, blood-tinged mucus and blood flecks (8%), pharyngitis (4%), nasal burning (2%), nasal irritation (2%) and nasal ulceration, which are typically observed with the use of a corticosteroid nasal spray. Epistaxis was generally self-limiting and mild in severity, and occurred at a higher incidence compared to placebo (5%), but at a comparable or lower incidence compared to other active control nasal corticoids used in clinical studies (up to 15%). The incidence of all other effects was comparable with that of placebo.

In the paediatric population, the most common adverse effects were epistaxis (6%), headache (3%), nasal irritation (2%) and sneezing (2%).

Rarely, immediate hypersensitivity reactions (eg. bronchospasm, dyspnea) may occur after intranasal administration of mometasone furoate monohydrate. Very rarely, anaphylaxis and angioedema have been reported.

Disturbances of taste and smell have been reported very rarely.

Adjunctive Treatment of Acute Episodes of Sinusitis

In adults and adolescent patients receiving Nasonex Aqueous Nasal Spray treatment-related adverse events which occurred at an incidence comparable to placebo, included headache (2%), pharyngitis (1%), nasal burning (1%) and nasal irritation (1%). Epistaxis was mild in severity (5%).

INTERACTIONS

Nasonex Aqueous Nasal Spray has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite. Mometasone furoate plasma concentrations were not detectable. The combination therapy was well tolerated.

OVERDOSAGE

Because of the negligible ($\leq 0.1\%$) systemic bioavailability of Nasonex Aqueous Nasal Spray, overdose is unlikely to require any therapy other than observation. Treatment can be reinitiated at the usual recommended dose.

PHARMACEUTICAL PRECAUTIONS

The shelf-life is 24 months when stored below 25°C. Do not freeze.

MEDICINE CLASSIFICATION

Prescription medicine

PACKAGE QUANTITIES

Boxes of 1 metered atomising pump unit containing mometasone furoate (as the monohydrate) 50 μ g/actuation; 65 and 140 metered doses.

FURTHER INFORMATION

Nasonex Aqueous Nasal Spray contains mometasone furoate (as the monohydrate) 0.5mg/g, dispersible cellulose BP 65 cps, glycerol, citric acid, sodium citric dihydrate, polysorbate 80 and purified water with benzalkonium chloride 0.2mg/g as preservative. Nasonex Aqueous Nasal Spray does not contain fluorocarbon propellants.

NAME AND ADDRESS

Merck Sharp & Dohme (NZ) Ltd
P O Box 99 851
Newmarket
Auckland 1149

Tel: 0800 500 673

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