Norhinose

L. Ver. 12

Nasal Spray

Composition:
Each metered dose contains:
Active ingredient:
Mometasone furoate monohydrate 0.052 mg
(Equivalent to 0.05 mg mometasone furoate)
Inactive ingredients:
Microcrystalline cellulose and Carmellose sodium (Type 591), Glycerin, Polysorbate 80, Sodium citrate dihydrate, Benzalkonium chloride, Citric acid anhydrous, Disodium edetate, and purified water.
PHARMACEUTICAL FORM
Nasal Spray.
Clinical particulars
Therapeutic indications
Norhinose Nasal Spray is indicated for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis.
Norhinose Nasal Spray is indicated for the treatment of nasal polyps in adults 18 years of age and older.
Posology and method of administration
After initial priming of the Norhinose Nasal Spray pump, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate.
Posology
Seasonal Allergic or Perennial Rhinitis
Adults (including older patients) and children 12 years of age and older: The usual recommended dose is two actuations (50 micrograms/actuation) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one actuation in each nostril (total dose 100 micrograms) may be effective for maintenance. If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of four actuations in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.
Children between the ages of 3 and 11 years: The usual recommended dose is one actuation (50 micrograms/actuation) in each nostril once daily (total dose 100 micrograms).
Norhinose Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; however, full benefit of treatment may not be achieved in the first 48 hours. Therefore, the patient should continue regular use to achieve full therapeutic benefit. Treatment with Norhinose Nasal Spray may need to be initiated some days before the expected start of the pollen season in patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis.
Nasal Polyposis
The usual recommended starting dose for polyposis is two actuations (50 micrograms/actuation) in each nostril once daily (total daily dose of 200 micrograms). If after 5 to 6 weeks symptoms are inadequately controlled, the dose may be increased to a daily dose of two sprays in each nostril twice daily (total daily dose of 400 micrograms). The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, the patient should be re-evaluated and treatment strategy reconsidered.
Paediatric population
Seasonal Allergic Rhinitis and Perennial Rhinitis
The safety and efficacy in children under 3 years of age have not been established.
Nasal Polyposis
The safety and efficacy in children and adolescents under 18 years of age have not been established.
Method of administration
Prior to administration of the first dose, shake container well and actuate the pump 10 times (until a uniform spray is obtained). If the pump is not used for 14 days or longer, reprime the pump with 2 actuations until a uniform spray is observed, before next use.
Shake container well before each use. The bottle should be discarded after the labelled number of actuations or within 2 months of first use.
Contraindications
Hypersensitivity to the active substance, mometasone furoate, or to any of the excipients. this Nasal Spray should not be used in the presence of untreated localized infection involving the nasal mucosa, such as herpes simplex.
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.
Special warnings and precautions for use
Immunosuppression
this 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, or systemic viral infections.
Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.
Local Nasal Effects
Following 12 months of treatment with this Nasal Spray in a study of patients with perennial rhinitis, there was no evidence of atrophy of the nasal mucosa; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype. Nevertheless, patients using this Nasal Spray over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localized fungal infection of the nose or pharynx develops, discontinuance of this Nasal Spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing this Nasal Spray.
This drug is not recommended in case of nasal septum perforation.
Norhinose Nasal Spray contains benzalkonium chloride. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.
Systemic Effects of Corticosteroids
Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioral effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).
Following the use of intranasal corticosteroids, instances of increased intraocular pressure have been reported.
Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
Patients who are transferred from long-term administration of systemically active corticosteroids to this 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 or symptoms of withdrawal (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.
Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.
Nasal Polyps
The safety and efficacy have not been studied for use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities.
Unilateral polyps that are unusual or irregular in appearance, especially if ulcerating or bleeding, should be further evaluated.
Effect on Growth in Paediatric Population
It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a Paediatric specialist.
Non-nasal Symptoms
Although this Nasal Spray will control the nasal symptoms in most patients, the concomitant use of appropriate additional therapy may provide additional relief of other symptoms, particularly ocular symptoms.
Interaction with other medicinal products and other forms of interaction
(See Special warnings and special precautions for use with systemic corticosteroids)
A clinical interaction study was conducted with loratadine. No interactions were observed.
Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.
Fertility, pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of mometasone furoate in pregnant women. As with other nasal corticosteroid preparations, this Nasal Spray should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.
Lactation
It is unknown whether mometasone furoate is excreted in human milk. As with other nasal corticosteroid preparations, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from this Nasal Spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.
Fertility
There are no clinical data concerning the effect of mometasone furoate on fertility.
Effects on ability to drive and use machines
None known.
Undesirable effects
Summary of the safety profile
Epistaxis was generally self-limiting and mild in severity for allergic rhinitis. In patients treated for nasal polyposis, the overall incidence of adverse events was similar to that observed for patients with allergic rhinitis.
Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.
Tabulated list of adverse reactions
Within each system organ class, adverse reactions are ranked by frequency. Frequencies were defined as follows: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100). The frequency of post-marketing adverse events is considered as "not known (cannot be estimated from the available data)".

Table 1: Treatment-related adverse reactions reported by system organ class and frequency

	Very common	Common	Not known
Infections and infestations		Pharyngitis Upper respiratory tract infection**	
Immune system disorders			Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea
Nervous system disorders		Headache	
Eye disorders			Glaucoma Increased intraocular pressure Cataracts Vision blurred
Respiratory, thoracic and mediastinal disorders	Epistaxis*	Epistaxis Nasal burning Nasal irritation Nasal ulceration	Nasal septum perforation
Gastrointestinal disorders		Throat irritation*	Disturbances of taste and smell

*recorded for twice daily dosing for nasal polyposis
**recorded at uncommon frequency for twice daily dosing for nasal polyposis
Paediatric population
epistaxis, headache, nasal irritation and sneezing.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via Human Pharmacovigilance Department –Egyptian Pharmaceutical Vigilance Center (EPVC)-Egyptian Drug Authority (EDA)
21Abd Elaziz Al Souad st.-Manial El-Roda-Cairo, PO Box: 11451
Tel: +2 02 23648046/ +2 02 23640368 / +2 02 23684381 Extensions (Tel):1303 Extension (Fax):1300
Fax: +2 02 2368419
Website: www.epvc.gov.eg
E-Mail: Pv.center@eda.mohealth.gov.eg.
Overdose
Symptoms
Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.
Management
Because the systemic bioavailability of this Nasal Spray is <1%, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.
Pharmacological properties
Pharmacodynamic properties
Pharmacotherapeutic group: Decongestants and Other Nasal Preparations for Topical Use
Mechanism of action
Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.
It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of mometasone furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients. In cell culture, mometasone furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNFα; it is also a potent inhibitor of leukotriene production. In addition, it is an extremely potent inhibitor of the production of the Th2 cytokines, IL-4 and IL-5, from human CD4+ T-cells.
Pharmacodynamic effects
In studies utilizing nasal antigen challenge, this drug has shown anti-inflammatory activity in both the early- and late- phase allergic responses. This has been demonstrated by decreases in histamine and eosinophil activity and reductions in eosinophils, neutrophils, and epithelial cell adhesion proteins.
In 28% of the patients with seasonal allergic rhinitis, this Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose. The median (50%) onset time of relief was 35.9 hours.
Pharmacokinetic properties
Absorption
Mometasone furoate, administered as an aqueous nasal spray, has a systemic bioavailability of <1% in plasma, using a sensitive assay with a lower quantitation limit of 0.25 pg/ml.
Distribution
Not applicable as mometasone is poorly absorbed via the nasal route.
Biotransformation
The small amount that may be swallowed and absorbed undergoes extensive first-pass hepatic metabolism.
Elimination
Absorbed mometasone furoate is extensively metabolized and the metabolites are excreted in urine and bile.
Storage condition
Store at temperature not exceeding 30 °C.
Shelf life
2 years
Package
Carton box containing an amber glass (Type III) bottle, containing 18 gm suspension of 120 doses with a white polypropylene plastic nasal sprayer with low density polyethylene dip tube surrounded by polypropylene housing cap capped with low density polyethylene plastic transparent cap + insert leaflet.

Manufactured by:
European Egyptian pharmaceutical Industries
For
Amriya for Pharmaceutical Industries
Alexandria - Egypt

AMRIYA PHARMACEUTICALS

Ahmed Samir 28/2/2021