NASONEX® Aqueous Nasal Spray
Mometasone Furoate

Schering-Plough

COMPOSITION

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

ACTIONS

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 potency in inhibition of synthesis and release of IL-I, IL-5, IL-6 and TNFa. It is also a potent inhibitor of leukotriene production. In addition, it is an inhibitor of the production of the Th 2 cytokines IL-4 and IL-5, from human CD 4 + T-cells. In studies utilizing 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 ephithelial cell adhesion proteins. In patients with seasonal allergic rhinitis, NASONEX® Aqueous Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose.

Pharmacokinetic Properties

Mometasone furoate, administered as an aqueous nasal spray, has a negligible (≤0.1%) systemic bioavailability and is generally undetectable in plasma, despite the use of sensitive assay with a lower quantitation limit of 50 pg/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 hepatic metabolism prior to excretion in urine and bile.

INDICATIONS

NASONEX® Aqueous Nasal Spray is indicated for use in adults, adolescents and children between the age of 2 and 11 years to treat the symptoms of seasonal or perennial rhinitis, especially in moderate to severe persistent allergy.

NASONEX® Aqueous Nasal Spray is also indicated for the treatment of nasal polyps in adult patients 18 years of age and older.

NASONEX® Aqueous Nasal Spray is indicated for the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis in adults and children 12 years of age and older where signs or symptoms of bacterial infection are not present.

DOSAGE AND ADMINISTRATION

Seasonal allergic or perennial rhinitis:

After initial priming of the NASONEX® Aqueous Nasal Spray (usually 6 or 7 actuations, until a uniform spray is released)-, each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 µg mometasone furoate. Prior to administration of the first dose, shake container well and actuate pump well before each use. If the product has not been used for 14 days or longer, it should be reprimed before next use.

Adults (including geriatric patients) and children 12 years of age and older-:

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

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

Children between the ages of 2 through 11 years :

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

Administration to young children should be aided by an adult.

Nasal polyposis: Adults (including geriatric patients) and adolescents 18 years of age and older: The usual recommended dose for polyposis is two sprays (50 micrograms/spray) in each nostril twice daily (total daily dose of 400 mcg). Once symptoms are adequately controlled, dose reduction to two sprays in each nostril once daily (total daily dose 200 mcg) is recommended.

Efficacy and safety studies of NASONEX® for the treatment of nasal polyps were four monts in duration.

Treatment of mild to moderate uncomplicated acute rhinosinusitis: The usual recommended dose for acute rhinosinusitis is two actuations (50 micrograms/actuation) in each nostril twice daily (total daily dose of 400 micrograms). If symptoms worsen during treatment, the patient should be advised to consult their physician.

Patients should not use NASONEX® without an antibiotic if bacterial infection of the sinuses is present or suspected.

If signs or symptoms of severe bacterial infection are observed during treatment (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately, at which time the physician may advise the patient to stop using NASONEX®.

Safety and efficacy of NASONEX® in the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis beyond 15 days have not been evaluated.

NASONEX® Aqueous Nasal Spray demonstrates a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; this was also shown in a clinical trial with NASONEX® Aqueous Nasal Spray. 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.

The therapeutic effects of corticosteroids, unlike those of decongestants, are not immediate. Since the effect of NASONEX® depends on its regular use, patients should be instructed to take the nasal inhalation at regular intervals and not, as with other nasal sprays, as they feel necessary.

In the presence of excessive nasal mucous secretion or edema of the nasal mucosa, the drug may fail to reach the site of action. In such cases, it is adviseable to use a nasal vasoconstrictor for 2 to 3 days prior to starting treatment with NASONEX®. Patients should be instructed on the correct method of use, which is to blow the nose, then insert the nozzle carefully into the nostril, compress the opposite nostril and actuate the spray while inspiring through the nose, with the mouth closed.

PRECAUTIONS

NASONEX® Aqueous Nasal Spray should not be used in the presence of untreated localized 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; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic 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 localized fungal infection of the nose or pharynx develops, discontinuance of NASONEX® Aqueous Nasal Spray 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 tuberculosis 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 measure instituted.

During transfer from systemic corticosteroids to NASONEX® Aqueous Nasal Spray, some patients may experience symptoms of withdrawal from systemically active corticosteroids (e.g., 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 (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

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

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses.

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 patient to a paediatric specialist.

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.

If signs or symptoms of severe bacterial infection are observed (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately.

Safety and efficacy of NASONEX® Aqueous Nasal Spray for the treatment of symptoms of rhinosinusitis in children under 12 years of age have not been studied.

The safety and efficacy of NASONEX® has 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.

Safety and efficacy of NASONEX® Nasal Spray for the treatment of nasal polyposis in children and adolescents under 18 years of age have not been studied.

USAGE DURING PREGNANCY & LACTATION

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

As with other nasal corticosteroid preparations NASONEX® Aqueous Nasal Spray should not be used in pregnant women, nursing mothers or women of childbearing age unless the potential benefit justifies the potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

OVER DOSAGE :

Because of the negligible (≤ 0.1%) systemic bioavailability of NASONEX® Aqueous Nasal Spray, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

ADVERSE EFFECTS

Seasonal allergic or perennial rhinitis: Treatment-related local adverse events reported in clinical studies include headache (8%), epistaxis (i.e., frank bleeding, blood-tinged mucus, and blood fleck) (8%), pharyngitis (4%), nasal burning (2%), nasal irritation (2%) and nasal ulceration (1%), which are typically observed with 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 the active control nasal corticosteroids studied (up to 15%). The incidence of all other effects was comparable with that of placebo.

In the pediatric population, the incidence of adverse effects, e.g., headache (3%), epistaxis (6%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

Rarely, immediate hypersensitivity reactions (e.g. 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.

Nasal Polyposis: In patients treated for nasal polyposis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

Acute rhinosinusitis: In patients treated for mild to moderate acute rhinosinusitis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

CONTRA INDICATIONS

Hypersensitivity to any ingredients of NASONEX® Aqueous Nasal Spray.
Should not be used in the presence of untreated localized 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.

PRESENTATIONS

Bottle of 60 mettered dose units : Reg. No. DKI0087100256A1

Bottle of 120 mettered dose units; Reg. No. DKl0087100256A1
Bottle of 140 mettered dose units ; Reg.No. DKl0087100256A1

Store below 30° C. Do not freeze

HARUS DENGAN RESEP DOKTER

Manufactured by :
Schering Plough Labo N.V., Belgium.
Imported by :
PT Schering-Plough Indonesia Tbk.,
Pandaan, East – Java,
A subsidiary of
Schering Plough Corporation, USA.

INSTRUCTIONS FOR USE

Proper administration of NASONEX is essential to achieve maximum efficacy and minimize the risk of complications. Caution: do not inject or cut spray pump with sharp device.
Nasonex Aqueous nasal spray is contained of the teal-blue plastic dust cap, spray pump and bottle (diagram 1)
Please read the instructions below carefully and use as recommended.

1. Remove the teal-blue plastic dust cap.

2. The very first time the spray is used or it is not used for 14 days or longer, it is necessary to prime the pump before use.
   Instruction: Prime the pump by pressing downwards on the white collar, using your forefinger and middle finger while supporting the base of the bottle with your thumb (diagram 2). Point nozzle away from you, shake container slowly and then press down and release the pump 6 – 7 times or until a fine spray appears.

3. Gently blow your nose to clear the nostrils.

4. Close one nostril, and carefully insert the nasal applicator into the other nostril. Tilt your head forward slightly, keeping the bottle upright. (diagram 3).

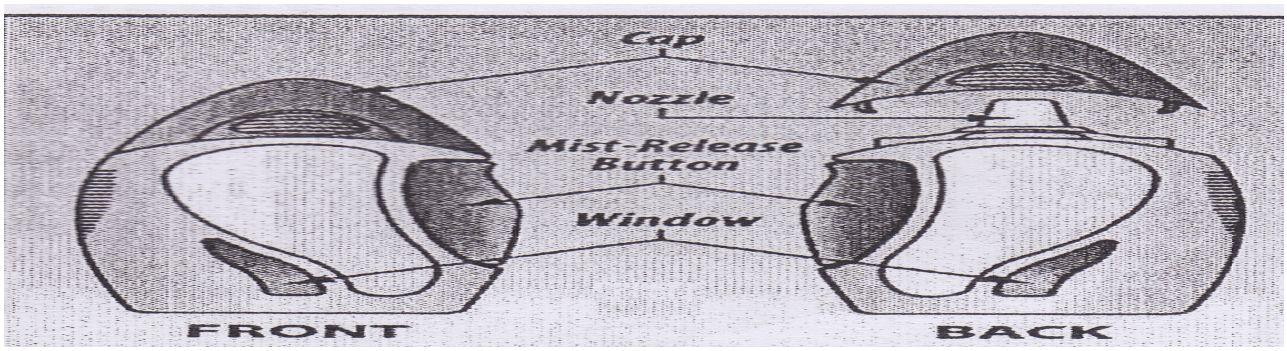
5. Start to breathe inward through the nostril and press firmly downward once on the shoulders of the white applicator.

6. Take out the spray from the nostril, then breathe out through the mouth.

7. Repeat steps 3 to 6 in other nostril. (diagram 4)

8. If you need two sprays for each nostril, spray both in one before moving to the other nostril.

9. After use, clean the spray pump and replace the plastic dust cap.


Cap
Nozzle
Mist-Release Button
Window
FRONT
BACK