

Rhinisone[®] Nasal Spray **50 mcg/actuation**

(Mometasone furoate 50 mcg/actuation)

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. Brand or Product Name

RHINISONE Nasal Spray (Mometasone furoate 50 mcg/actuation)

2. Name and Strength of Active Substance(s)

Mometasone furoate 50 mcg/actuation (corresponding to 51.73mcg/actuation of mometasone furoate monohydrate)

Excipient with known effect:

This medicinal product contains 0.02 mg of benzalkonium chloride per actuation.

3. Product Description

Mometasone suspension is a nasal spray, white to off white viscous suspension containing 50 µg/actuation of mometasone furoate anhydrous (corresponding to 51.73 µg/actuation of mometasone furoate monohydrate).

4. Pharmacodynamics

In studies utilizing nasal antigen challenge, Mometasone 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.

In clinical trials with nasal polyposis, Mometasone Nasal Spray showed significant improvement when compared to placebo in the clinically relevant endpoints of congestion, nasal polyp size and loss of smell.

5. Pharmacokinetics

Mometasone furoate, administered as a nasal spray, has a systemic bioavailability of <1% in plasma, using a sensitive assay with a lower quantitation limit (LLOQ) of 0.25 pg/ml. 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 mostly as metabolites in the bile and to a limited extent in the urine.

6. Indication

RHINISONE Nasal Spray is indicated for use in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of seasonal or perennial rhinitis.

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

RHINISONE Nasal Spray is also indicated for the treatment of nasal polyps in patients 18 years of age and older.

RHINISONE Nasal Spray is indicated for the treatment of symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.

7. Recommended Dosage

After initial priming of the RHINISONE Aqueous Nasal pump (10 actuations, until a uniform spray is observed), each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed with 2 actuations, until a uniform spray is observed, before next use.

Shake container well before each use.

Seasonal allergic or perennial rhinitis: Adults (including geriatric patients) and adolescents: The usual recommended dose for prophylaxis and treatment is two sprays (50 micrograms/spray) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one spray 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 sprays in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.

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

Children between the ages of 3 and 11 years: The usual recommended dose is one spray (50 micrograms/spray) in each nostril once daily (total dose 100 micrograms).

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.

Acute Rhinosinusitis: Adults (including geriatric patients) and adolescents 12 years of age or older: 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 no improvement is seen after 15 days of twice daily administration, alternative therapies should be considered. If symptoms worsen during treatment, the patient should be advised to consult their physician.

8. Route of Administration

Nasal.

9. Contraindications

Hypersensitivity to any ingredients of RHINISONE Nasal Spray; severe nasal infection especially candidiasis; persons with hemorrhagic diathesis or with a history of recurrent nasal bleeding.

10. Warnings and Precautions

RHINISONE 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 mometasone furoate 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 RHINISONE 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 RHINISONE Nasal Spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing RHINISONE Nasal Spray.

RHINISONE 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 RHINISONE Nasal Spray. However, patients who are transferred from long-term administration of systemically active corticosteroids to RHINISONE 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.

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.

In a placebo-controlled clinical trial in which pediatric patients were administered Mometasone furoate 100 micrograms daily for one year, no reduction in growth velocity was observed.

Safety and efficacy of RHINISONE Nasal Spray for the treatment of nasal polyposis in children and adolescents less than 18 years of age have not been studied.

During transfer from systemic corticosteroids to RHINISONE Nasal Spray, some patients may experience symptoms of



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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 RHINISONE 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.

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.

Acute Rhinosinusitis

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 RHINISONE Nasal Spray for the treatment of symptoms of rhinosinusitis in children under 12 years of age have not been studied. General Nasal Corticosteroid Warning: 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.

11. Drug Interactions

Mometasone Furoate Nasal Spray has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite. In these studies, mometasone furoate plasma concentrations were not detectable using an assay with a LLOQ of 50 pg/ml. The combination therapy was well tolerated.

Mometasone furoate is metabolized by CYP3A4.

Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing products) may lead to increased plasma concentrations of corticosteroids and potentially increase the risk for systemic corticosteroid side-effects. Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side-effects.

12. Pregnancy and Lactation

There are no adequate or well controlled studies in pregnant women.

As with other nasal corticosteroid preparations, RHINISONE Nasal Spray should be used in pregnant women, nursing mothers or women of childbearing age only if 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.

13. Side Effects

Summary of the safety profile

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 when compared to the active control nasal corticosteroids studied (up to 15%) as reported in clinical studies for allergic rhinitis. The incidence of all other adverse events was comparable with that of placebo. 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

Treatment related adverse reactions ($\geq 1\%$) reported in clinical trials in patients with allergic rhinitis or nasal polyposis and post-marketing regardless of indication are presented in Table 1. Adverse reactions are listed according to MedDRA primary system organ class. Within each system organ class, adverse reactions are ranked by frequency. Frequencies were defined as follows: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$). The frequency of post-marketing adverse events are considered as "not known (cannot be estimated from the available data)".

	Very common	Common	Not known
Infections and infestations		Pharyngitis Upper respiratory tract infection ¹	
Immune system disorders			Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea
Nervous system disorders		Headache	
Eye disorders			Glaucoma Increased intraocular pressure Cataracts Vision blurred (see also section 4.4)
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

Paediatric population

In the paediatric population, the incidence of recorded adverse events in clinical studies, e.g., epistaxis (6%), headache (3%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

14. Symptoms and Treatment of Overdose

Because the systemic bioavailability of RHINISONE Nasal Spray is $< 1\%$, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

15. Storage Conditions

Store below 30° C. Please store in cool dry place and away from heat. Do not freeze. Use within 2 months after the first use.

16. Dosage forms and packaging available

Each unit of RHINISONE Nasal Spray delivers 60 actuations or 140 actuations: containing 50 micrograms mometasone furoate per actuation

17. Name and address of the product registration holder

Aetos Pharma Sdn Bhd (1322949-D)

Add: No. 66B-Tingkat 2, Jalan Cerdas,
Taman Connaught,
56000 Kuala Lumpur, Malaysia

18. Date of revision of PI

The latest date of this PI is revised is 15-04-2026

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