Summary of Product Characteristic (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

MOMATE NASAL SPRAY

1. NAME OF THE MEDICINAL PRODUCT

Momate Nasal Spray (Mometasone Furoate Monohydrate Nasal Spray 50 mcg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Mometasone Furoate Monohydrate
equivalent to Mometasone Furoate .....0.05% w/w

Each spray delivers:

Mometasone Furoate Monohydrate equivalent to Mometasone Furoate .....50 mcg

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Nasal Spray

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mometasone Furoate 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.

Mometasone Furoate Nasal Spray is indicated for the treatment of nasal polyps in adults 18 years of age and older.

4.2 Posology and method of administration

After initial priming of the Mometasone Furoate Nasal Spray pump, each actuation delivers approximately 100 mg of mometasone furoate suspension, 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).

Mometasone furoate 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 mometasone furoate 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 reevaluated and treatment strategy reconsidered.

Efficacy and safety studies of mometasone furoate nasal spray for the treatment of nasal polyposis were four months in duration.

Paediatric population

Seasonal Allergic Rhinitis and Perennial Rhinitis

The safety and efficacy of mometasone furoate nasal spray in children under 3 years of age have not been established.

Nasal Polyposis

The safety and efficacy of mometasone furoate nasal spray 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 labeled number of actuations (120 doses) or within 2 months of first use.

4.3 Contraindications

Hypersensitivity to the active substance mometasone furoate or to any of the excipients listed in section 6.1.

Mometasone furoate nasal spray should not be used in the presence of untreated localised 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.

4.4 Special warnings and special precautions for use

Immunosuppression

Mometasone furoate 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 mometasone furoate 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 mometasone furoate 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

mometasone furoate nasal spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing mometasone furoate nasal spray.

Mometasone Furoate is not recommended in case of nasal septum perforation.

In clinical studies, epistaxis occurred at a higher incidence compared to placebo. Epistaxis was generally self-limiting and mild in severity.

Mometasone Furoate Nasal Spray contains benzalkonium chloride which 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 behavioural 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 mometasone furoate 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 preexisting 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 of mometasone furoate nasal spray 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.

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 mometasone furoate 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.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Fertility, pregnancy and lactation

Fertility

There are no clinical data concerning the effect of mometasone furoate on fertility. Animal studies have shown reproductive toxicity, but no effects on fertility.

Pregnancy

There are no or limited amount of data from the use of mometasone furoate in pregnant women. Studies in animals have shown reproductive toxicity. As with other nasal corticosteroid preparations, mometasone furoate nasal spray should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, foetus 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 breastfeeding or to discontinue/abstain from mometasone furoate nasal spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines None known.

4.8 Undesirable 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 (≥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 (≥1/10); common (≥1/100 to <1/10); uncommon (≥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)”.

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 dyspnea
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*	Disturbance 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

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product 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 to the National Regulatory Authority.

4.9 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 mometasone furoate nasal spray is <1%, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestants and Other Nasal Preparations for Topical UseCorticosteroids, ATC code: R01A D09

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 IL1, IL5, IL6 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, IL4 and IL5, from human CD4+ T-cells.

Pharmacodynamic effects

In studies utilising nasal antigen challenge, mometasone furoate nasal spray has shown antiinflammatory 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 28% of the patients with seasonal allergic rhinitis, mometasone furoate 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.

Paediatric population

In a placebo-controlled clinical trial in which paediatric patients (n=49/group) were administered mometasone furoate nasal spray 100 micrograms daily for one year, no reduction in growth velocity was observed.

There are limited data available on the safety and efficacy of mometasone furoate nasal spray in the paediatric population aged 3 to 5 years, and an appropriate dosage range cannot be established. In a study involving 48 children aged 3 to 5 years treated with intranasal mometasone furoate 50, 100 or 200 µg/day for 14 days, there was no significant differences from placebo in the mean change in plasma cortisol level in response to the tetracosactrin stimulation test.

The European Medicines Agency has waived the obligation to submit the results of studies with mometasone furoate nasal spray and associated names in all subsets of the paediatric population in seasonal and perennial allergic rhinitis.

5.2 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.

5.3 Preclinical safety data

No toxicological effects unique to mometasone furoate exposure were demonstrated. All observed effects are typical of this class of compounds and are related to exaggerated pharmacologic effects of glucocorticoids.

Preclinical studies demonstrate that mometasone furoate is devoid of androgenic, antiandrogenic, estrogenic or anti-estrogenic activity but, like other glucocorticoids, it exhibits some anti-uterotrophic activity and delays vaginal opening in animal models at high oral doses of 56 mg/kg/day and 280 mg/kg/day.

Like other glucocorticoids, mometasone furoate showed a clastogenic potential *in vitro* at high concentrations. However, no mutagenic effects can be expected at therapeutically relevant doses.

In studies of reproductive function, subcutaneous mometasone furoate, at 15 micrograms/kg prolonged gestation and prolonged and difficult labour occurred with a reduction in offspring survival and body weight or body weight gain. There was no effect on fertility.

Like other glucocorticoids, mometasone furoate is a teratogen in rodents and rabbits. Effects noted were umbilical hernia in rats, cleft palate in mice and gallbladder agenesis, umbilical hernia, and flexed front paws in rabbits. There were also reductions in maternal body weight gains, effects on foetal growth (lower foetal body weight and/or delayed ossification) in rats, rabbits and mice, and reduced offspring survival in mice.

The carcinogenicity potential of inhaled mometasone furoate (aerosol with CFC propellant and surfactant) at concentrations of 0.25 to 2.0 micrograms/L was investigated in 24-month studies in mice and rats. Typical glucocorticoid-related effects, including several nonneoplastic lesions, were observed. No statistically significant dose-response relationship was detected for any of the tumour types.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

MCC and CMC Sodium,
Glycerol,
Citric Acid Monohydrate,
Sodium Citrate,
Polysorbate 80,
Benzalkonium Chloride,
Water for Injection.

6.2Incompatibilities

Not Applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at temperature below 30°C. Do not freeze. Protect from Light.

6.5 Nature and contents of container

A printed carton containing a leaflet and a labeled crimp on opaque HDPE bottle crimped with nasal spray pump, fitted with an actuator and cap.

6.6 Special precautions for disposal and other handling

Keep away from Children. Shake well before use.

7. Marketing Authorization Holder

Manufactured by:
Glenmark Pharmaceuticals Ltd.
B/2, Mahalaxmi
Chambers, 22,
Bhulabhai Desai road,
Mumbai – 400 026.

Manufactured at:

UNIT - III, Village Kishanpura,
Baddi - Nalagarh Road,
Tehsil Baddi, Distt. Solan, (H.P.) -173 205, INDIA

8. **Marketing Authorisation number**

H2019/TD3863/1219ER

9. Date of First Authorization/ renewal of authorization

10-04-2019

10. Date Of Revision Of The Text

April 2026