PROFESSIONAL INFORMATION

RHINIMET

SCHEDULING STATUS

Schedule 2

1. NAME OF THE MEDICINE

RHINIMET (Nasal Spray).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation delivers 100 mg **RHINIMET** Nasal Spray which contain 0,05175 mg mometasone furoate monohydrate equivalent to 0,050 mg mometasone furoate.

RHINIMET contains benzalkonium chloride solution (50 % *w/v*) 0,040 % *m/m* as preservative.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Nasal Spray

White off homogenous aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RHINIMET Nasal Spray is indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults, adolescents and children between the age of 2 and 11 years of age.

Prophylactic treatment: The use of **RHINIMET** Nasal Spray, prior to the anticipated start of the pollen season, is recommended for patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis.

4.2 Posology and method of administration

Seasonal Allergic or Perennial Rhinitis

Adults (including elderly patients) and adolescents: The usual recommended dose for prophylaxis and treatment is two sprays (0,05 mg/actuation) in each nostril once a day (total dose 0,2 mg).

If symptoms are not adequately controlled, the dose may be increased to a maximum daily dose of four sprays in each nostril once a day (total dose 0,4 mg). Dose reduction is recommended once symptoms are under control.

Children between the ages of 2 and 11 years: The usual recommended dose is one spray (0,05 mg/actuation) in each nostril once a day (total dose 0,1 mg).

An adult should aid the administration of **RHINIMET** Nasal Spray to young children.

Paediatric population

The safety and efficacy of **RHINIMET** Nasal Spray in children under 2 years of age have not been established.

Method of administration

Shake container well before each use.

Priming:

Prime the **RHINIMET** Nasal Spray pump with approximately 10 actuations, until a uniform spray is formed.

If the nasal spray is not used for 14 days or longer, re-prime the nasal spray with 2 actuations until a uniform spray is formed, before next use.

4.3 Contraindications

RHINIMET Nasal Spray is contraindicated in patients with a known hypersensitivity to

mometasone furoate or any of the excipients listed in Section 6.1.

RHINIMET Nasal Spray should not be used during pregnancy and breastfeeding (see Section 4.6).

RHINIMET Nasal Spray should not be used in children under 2 years, as safety and efficacy has not been established.

4.4 Special warnings and precautions for use

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

RHINIMET Nasal Spray should not be used in patients who have experienced recent nasal surgery or trauma, due to the inhibitory effect of corticosteroids on wound healing. Therapy with **RHINIMET** Nasal Spray should not be initiated until healing has occurred.

Immunosuppression

In patients who present with active or dormant tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex, **RHINIMET** Nasal Spray should be used with caution, if at all.

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

Local Nasal Effects

In a study of patients with perennial rhinitis, there was no evidence of atrophy of the nasal mucosa following 12 months of treatment with mometasone (in a nasal spray). In addition, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype.

Nevertheless, the nasal mucosa of patients using **RHINIMET** Nasal Spray for several months or longer should be examined periodically for possible changes. **RHINIMET** Nasal Spray therapy should be discontinued or appropriate treatment may be required if localised fungal infection of the nose or pharynx develops. **RHINIMET** Nasal Spray must be discontinued if the nasopharyngeal irritation persists.

The use of **RHINIMET** Nasal Spray is not recommended in case of nasal septum perforation (see Section 4.8).

Studies have demonstrated that epistaxis occurred at a higher incidence with the use of mometasone furoate compared to the placebo. Epistaxis was generally self-limiting and mild in severity (see Section 4.8).

Systemic Effects of Corticosteroids

Nasal corticosteroids may cause systemic effects,especially at high doses prescribed for prolonged periods, however these effects are less likely to occur than with oral corticosteroids. This may vary in individual patients and between different corticosteroid preparations.

Potential systemic effects may include adrenal suppression, cataract, Cushing's syndrome, Cushingoid features, glaucoma, growth retardation in children and adolescents, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (especially in children).

Following the use of nasal sprays containing corticosteroids, instances of increased intraocular pressure have been reported (see Section 4.8).

Visual disturbance may occur 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 referred 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 occurred after use of systemic and topical corticosteroids.

Careful attention is required in patients who are transferred from long-term administration of

systemically active corticosteroids to **RHINIMET** Nasal Spray. Patients may experience adrenal insufficiency due to systemic corticosteroid withdrawal, for a number of months until the hypothalmic-pituitary-adrenal (HPA) axis function is recovered. If signs and symptoms of adrenal insufficiency or symptoms of withdrawal (such as joint and/or muscular pain, lassitude, and depression initially) is exhibited in these patients, systemic corticosteroid administration should be restarted and other modes of therapy and appropriate measures instituted, despite relief from nasal symptoms.

These patients may require encouragement to continue therapy with **RHINIMET** Nasal Spray.

This transfer may also unmask pre-existing allergic conditions, including allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Clinically significant adrenal suppression may result if treatment with higher than recommended doses is prescribed. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid therapy should be considered during periods of stress or elective surgery.

Effect on Growth in Paediatric Population

Children receiving prolonged treatment with nasal corticosteroids should have their height regularly monitored. If growth is slowed, therapy should be reviewed with the aim of decreasing the dose of **RHINIMET** Nasal Spray if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, referring the patient to a paediatric specialist should be considered.

Non-nasal Symptoms

Although **RHINIMET** Nasal Spray will control the nasal symptoms in most patients, the co-administration of **RHINIMET** Nasal Spray with appropriate additional therapy may result in additional relief of other symptoms, especially ocular symptoms.

RHINIMET Nasal Spray contains benzalkonium chloride which may cause nasal irritation or swelling inside the nose, especially following prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

A clinical interaction study was conducted with mometasone furoate and loratadine. No apparent effect on plasma concentrations of loratadine or its major metabolite was observed. Mometasone furoate plasma concentrations were undetectable.

Mometasone furoate is metabolised by CYP3A4.

Co-administration with strong CYP3A inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing medicines), may lead to–increased plasma concentrations of corticosteroids and potentially increase the risk of systemic side effects. This combination should be avoided unless the benefit justifies the increased risk of systemic corticosteroid side effects. In this case patients should be monitored for systemic corticosteroid side effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited data on the use of mometasone furoate in pregnant women. Studies in animals have demonstrated reproductive toxicity. **RHINIMET** should not be used during pregnancy (see Section 4.3).

Lactation

It is not known whether mometasone furoate is excreted in human milk.**RHINIMET** should not be used during lactation (see Section 4.3).

Fertility

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

4.7 Effects on ability to drive and operate machinery

Dizziness may occur following administration of **RHINIMET**, which may affect the ability to drive and use machines (see Section 4.8).

4.8 Undesirable effects

The following side effects are associated with **RHINIMET:**

Infections and infestations	
Frequent	Pharyngitis, upper respiratory tract infection.
Immune system disorders	
Frequency unknown:	Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea.
Nervous system disorders:	
Frequent	Dizziness
Eye disorders	
Frequency unknown:	Dry eyes, conjuctivitis, glaucoma, increased intraocular pressure, cataracts, vision blurred.
Respiratory, thoracic and mediastinal disorders	
Frequent:	Epistaxis*, pharyngitis, nasal burning, nasal irritation and nasal ulceration.
Frequency unknown	Nasal septum irritation, rhinorrhoea, cough, nasal septum perforation, rhinitis, sinisitis.
Gastrointestinal disorders:	
Frequent	Throat irritation
Frequency unknown	Disturbances of tast and smell, and nausea
Skin and subcutaneous tissue disorders	
Frequency unknown	Skin rash
General disorders and administration site conditions	

Frequent	Headache

*Epistaxis was generally self-limiting and mild in severity

Paediatric population

The incidence of recorded side effects based on studies include: epistaxis, headache, nasal irritation and sneezing.

Reporting of suspected adverse reactions

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

4.9 Overdose

Signs and symptoms

Symptoms

Excessive doses of corticosteroids (by inhalation or oral administration) may lead to suppression of the hypothalmic-pituitary-adrenal axis function.

Management

Because the systemic bioavailability of mometasone (in a nasal spray) is < 0,1 %, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate required dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties:

Pharmacological Class: A 21.5.1 Corticosteroids and analogues.

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use-

corticosteroids

ATC code: R01AD09

PHARMACOLOGICAL ACTION

Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients: Benzalkonium chloride, citric acid monohydrate, glycerol, microcrystalline cellulose – carmellose sodium, polysorbate 80, purified water and sodium citrate dehydrate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from heat.

Do not freeze.

Store in the original packaging.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

RHINIMET Nasal Spray is a metered dose nasal spray contained in white HDPE crimp on bottle, metered dose micro pump, nasal adaptor and transparent dust protective cap. This is packaged in a cardboard box.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

8 REGISTRATION NUMBER(S)

52/21.5.1/0538

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 06 July 2021

10 DATE OF REVISION OF THE TEXT

Not applicable