PROFESSIONAL INFORMATION FOR ZOMATE NS

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ZOMATE NS
(50 micrograms (µg)/actuation, Aqueous Nasal Spray)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose pump actuation of ZOMATE NS delivers mometasone furoate (as monohydrate) 50 micrograms (µg)/actuation.
ZOMATE NS contains benzalkonium chloride 0,02 % m/m per actuation (as preservative).
Sugar free.

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Aqueous Nasal Spray.
White to off-white viscous suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ZOMATE NS is indicated for use in adults, adolescents and children between the ages of 2 and 11 years to treat the symptoms of seasonal allergic or perennial allergic rhinitis.
In patients who have a history of moderate to severe symptoms seasonal allergic rhinitis, prophylactic treatment with ZOMATE NS is recommended prior to the anticipated start of the pollen season.

4.2 Posology and method of administration

Posology

After initial priming of the ZOMATE NS pump (usually 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 µg mometasone furoate.

Adults and adolescents

The usual recommended dose for prophylaxis and treatment is 2 sprays (50 µg/spray) into each nostril once daily (total dose 200 µg). Once symptoms are controlled, dose reduction to 1 spray into each nostril (total dose 100 µg) may be effective in some patients for maintenance.

If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of 4 sprays into each nostril once daily (total dose 400 µg). Dose reduction is recommended following control of symptoms.

Children between the ages of 2 and 11 years

The usual recommended dose is 1 spray (50 µg/spray) into each nostril once daily (total dose 100 µg). Administration to young children should be aided by an adult.

Paediatric populations

Safety and efficacy have not been established in children younger than 2 years old (see Section 4.3).

Method of administration

Prior to administration of the first dose, shake container well and actuate the pump approximately 10 times (until a uniform spray is obtained). If the pump is not used for 14 days or longer, re-prime the pump with approximately 2 actuations until a uniform spray is observed, before next use. No priming is needed subsequent to the initial priming is required with regular 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.

4.3 Contraindications

ZOMATE NS is contraindicated in:

- Patients with hypersensitivity to mometasone furoate or to any of the excipients (listed in Section 6.1);
- Pregnancy and lactation (see Section 4.6);
- Children under 2 years. Safety and efficacy have not been established (see Section 4.2).

4.4 Special warnings and precautions for use

Immunosuppression

ZOMATE NS 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.

Nasal inspection before and during use

Patients using ZOMATE NS 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 ZOMATE NS therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing ZOMATE NS.
ZOMATE NS should not be used in the presence of an untreated localised infection involving the nasal mucosa.
Due to the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use ZOMATE NS until healing has occurred.

Septum perforation

ZOMATE NS is not recommended in case of nasal septum perforation (see Section 4.8).

Epistaxis

Epistaxis may occur and is generally self-limiting and mild in severity (see Section 4.8).

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).

Instances of increased intraocular pressure may occur following the use of intranasal corticosteroids (see Section 4.8).

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 ZOMATE NS 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.

Non-nasal symptoms

Although ZOMATE NS 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.

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.

Excipients

ZOMATE NS contains benzalkonium chloride which may cause nasal irritation.

4.5 Interaction with other medicines and other forms of interaction

Mometasone furoate has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite. Mometasone furoate plasma concentrations were not detectable.

Mometasone furoate is metabolised by CYP3A4.

Co-treatment 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. 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

Safety during pregnancy and lactation has not been established (see Section 4.3).

Pregnancy

Animal studies have shown reproductive toxicity. ZOMATE NS is contraindicated in pregnancy (see Section 4.3).

Lactation

It is unknown whether mometasone furoate is excreted in human milk. ZOMATE NS is contraindicated during lactation (see Section 4.3).

Fertility

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

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

a. Tabulated summary of adverse reactions

System Organ Class	Frequency	Undesirable effect
Infections and infestations	*Frequent*	Pharyngitis, upper respiratory infections.
	Frequency unknown	Rhinitis, sinusitis.
Immune system disorders	*Less frequent*	Hypersensitivity including allergic reactions, angioedema, bronchospasm and dyspnoea.
Nervous system disorders	*Frequent*	Headache.
Eye disorders	*Frequency unknown*	Glaucoma, increased intraocular pressure, cataracts, blurred vision, conjunctivitis, dry eyes.
Respiratory, thoracic and mediastinal disorders	*Frequent*	Epistaxis, nasal burning, nasal irritation, nasal ulceration, sneezing.
	Less frequent	Nasal septum perforation, coughing, rhinorrhoea.

Gastrointestinal disorders	*Frequent*	Throat irritation.
	Less frequent	Taste and smell disturbances, nausea.
General disorders and administrative site disorders	*Frequency unknown*	Dizziness.
Skin and subcutaneous tissue disorders	*Frequency unknown*	Skin rash.

b. Paediatric populations

In paediatric populations, the following incidences of adverse events may occur, e.g., epistaxis, headache, nasal irritation and sneezing.

c. Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function. Systemic bioavailability of ZOMATE NS is less than 0,1 %. Overdosage with ZOMATE NS is therefore unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A. 21.5.1 Corticosteroids and analogues
Pharmacotherapeutic Group: Decongestants and other nasal preparations for topical use corticosteroids
ATC Code: R01AD09

Mechanism of action

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

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

Mometasone furoate 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride (preservative)
Glycerol
Polysorbate 80
Dispersible cellulose (microcrystalline cellulose and carmellose sodium)
Citric acid monohydrate
Sodium citrate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
Use within 2 months of first use.

6.4 Special precautions for storage

Store at or below 25 ºC.

6.5 Nature and contents of container

ZOMATE NS is contained in a white, high density polyethylene bottle, that contains 10 g (60 actuations), 16 g (120 actuations) or 18 g (140 actuations) of product formulation, supplied with a metering pump and on which a nasal applicator with cap is fitted.

Pack sizes: 10 g (60 actuations)
16 g (120 actuations)
18 g (140 actuations)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 HOLDERS OF CERTIFICATE OF REGISTRATION

Trinity Pharma (Pty) Ltd.
106 16th Road
Midrand
South Africa
1686

8 REGISTRATION NUMBER(S)

50/21.5.1/0292

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

06 July 2021

10 DATE OF REVISION OF THE TEXT

30 June 2021