Professional Information for NASACOR® T (55 µg Triamcinolone acetonide) Nasal spray

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

NASACOR® T 55 µg nasal spray, suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle of NASACOR T contains 16,5 g of suspension (with 9,075 mg triamcinolone acetonide).

One delivered dose contains 55 micrograms of triamcinolone acetonide.

Excipients with known effect:

Preservative: Benzalkonium chloride solution 0,015 % *m/m*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension.

NASACOR T nasal spray is a metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in a thixotropic aqueous medium.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NASACOR T nasal spray is indicated for the preventative treatment of seasonal and perennial allergic rhinitis symptoms in adults and children over 2 years of age.

4.2 Posology and method of administration

Posology

Adults and children 12 years of age and older

It is recommended that dosing be started at 220 µg as two sprays in each nostril once daily. Once

symptoms are controlled, patients can be maintained on 110 µg (one spray in each nostril once daily). Patients are provided with a check-off form to track usage of medication sprays.

Paediatric population

Children aged 6 to 12 years:

The recommended dose is 110 µg as 1 spray in each nostril daily. In patients with more severe symptoms, a dose of 220 µg (2 sprays in each nostril once daily) may be used. Once symptoms are controlled, patients should be maintained on the lowest effective dose.

Children aged 2 to 5 years:

The recommended and maximum dose is 110 µg per day as one spray in each nostril once daily.

Children under 2 years of age:

The safety and efficacy of NASACOR T in children under 2 years of age have not been established, therefore, use in this group of patients is currently not recommended.

Until further evidence is available, continuous use beyond 3 months in children under 12 years is not recommended.

Initial assessment for response should be made during the first three to four days and periodically until the patient's symptoms are stabilised. Some relief can be obtained in approximately two thirds of patients in that time. If adequate relief of symptoms has not been obtained after 3 weeks of treatment, NASACOR T nasal spray should be discontinued, and consideration to alternate forms of treatment should be given.

It is always desirable to titrate an individual patient to the minimum effective dose to reduce the possibility of side effects.

Method of administration

NASACOR T is for nasal use only.

Shake the bottle well before each use because NASACOR T is a thixotropic formulation.

Each actuation delivers 55 µg triamcinolone acetonide from the nasal actuator to the patient after an initial priming of 5 sprays until a fine mist is achieved. The product will remain adequately primed for 2 weeks. If the product is not used for more than 2 weeks, then it can be adequately reprimed with one spray. After the initial 5 priming sprays, there are at least 120 actuations in one NASACOR T nasal spray bottle. After 120 actuations, the amount of triamcinolone acetonide delivered per actuation may not be consistent and the unit should be discarded. Patients are provided with a check-off form to track usage of medication sprays. Do not exceed the prescribed dosage.

Illustrated patient's instructions for use accompany each package of NASACOR T nasal spray.

4.3 Contraindications

Hypersensitivity to triamcinolone acetonide or to any of the excipients listed in section 6.1.

Oral corticosteroids have been shown to cause growth suppression in children and teenagers, particularly with higher doses over extended periods. If a child or teenager on any corticosteroid appears to have growth suppression, the possibility that they are particularly sensitive to this effect of steroids should be considered.

4.4 Special warnings and precautions for use

The use of NASACOR T in combination with oral corticosteroids could increase the likelihood of hypothalamic-hypopituitary adrenal suppression compared to a therapeutic dose of either one alone. Therefore, NASACOR T should be used with caution in patients already receiving corticosteroids.

If there is any reason to suppose that adrenal function is impaired, care must be taken while transferring patients from systemic steroid treatment to NASACOR T, in addition, some patients may experience symptoms of withdrawal, e.g. joint and/or muscular pain, lassitude and depression. Patients previously treated for prolonged periods with systemic corticosteroids prior to transfer to topical corticosteroids, such as NASACOR T, nasal spray should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical

conditions requiring long-term systemic corticosteroid treatment, too rapid a decrease in systemic corticosteroids may cause a severe exacerbation of their symptoms.
Patients who are on immunosuppressant doses of corticosteroids should take particular care to avoid exposure to chickenpox and measles. In susceptible patients specific immunoglobulin or antiviral therapy may be indicated.

In clinical studies with NASACOR T nasal spray, the development of localised infections of the nose and pharynx with *Candida albicans* has rarely occurred. When such an infection develops it may require treatment with appropriate local therapy and temporary discontinuation of treatment with NASACOR T nasal spray.

NASACOR T nasal spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract or in patients with untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex.

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, NASACOR T nasal spray should be used with caution, until healing has occurred.
Nasal septal perforations have been reported in rare instances.

Systemic effects of nasal corticosteroids may occur, particularly when used for a prolonged duration or 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 (may vary as per the potency, dosage form and pharmacokinetic properties (lipophilicity, volume of distribution and elimination half-life) of the steroid). 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).

Treatment with higher than recommended doses may result in clinically significant adrenal suppression or hypercorticism.
If such changes occur, NASACOR T nasal spray should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.

The risks associated with sudden discontinuation of all corticosteroids after prolonged use may include exacerbation or recurrence of the underlying disease, adrenocortical insufficiency or steroid withdrawal syndrome. However, these effects are extremely rare for nasal corticosteroids, and much less likely to occur with nasal corticosteroids than with oral corticosteroids.
Typical signs and symptoms can be either systemic (e.g. arthralgia, myalgia, tremors, weight loss and anxiety) or localised (e.g. nasal bleeding, nasal drip).

Visual disturbance may be reported with systemic and topical 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 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.

Glaucoma and/or cataracts have been reported in patients receiving nasal corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma and/or cataracts.

Paediatric population
NASACOR T is not recommended for use in children under 2 years of age.
Reduction in growth velocity has been reported in children receiving nasal corticosteroids, including NASACOR T at licensed doses.
It is recommended that the height of children receiving treatment with nasal corticosteroids is regularly monitored. Therapy should be managed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained.

The long-term effects of reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height are unknown. In addition, consideration should be given to referring the patient to a paediatric specialist, especially for children under the age of 6 years this is strongly recommended.

Preservative warning

NASACOR T contains benzalkonium chloride as preservative. Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicines and other forms of interaction

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

Pregnancy

Clinical experience in pregnant women is limited.

In animal studies corticosteroids have been shown to induce teratogenic effects.

Therefore, NASACOR T should not be used during pregnancy.

Hypoadrenalism may occur in infants born to mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

Breastfeeding

Safety has not been established.

NASACOR T may pass into human breast milk. Therefore, NASACOR T should not be administered to nursing women.

Fertility

No data are available.

4.7 Effects on ability to drive and use machines

NASACOR T has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly reported adverse reactions included those involving mucous membranes of the nose and throat.

The following frequency rating has been used to classify the occurrence of undesirable effects: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000) and not known (cannot be estimated from available data).
The most frequent adverse reactions in adults and children 2 years of age and older were:

Infections and infestations

Common: flu syndrome, pharyngitis, rhinitis

Immune system disorders

Not known: hypersensitivity (including rash, urticaria, pruritus and facial oedema)

Endocrine disorders

Not known: steroid withdrawal syndrome

Psychiatric disorders

Not known: insomnia

Nervous system disorders

Common: headache

Not known: dizziness, alterations of taste and smell

Eye disorders

Not known: chorioretinopathy, cataract, glaucoma, increased ocular pressure, blurred vision (see also section 4.4)

Respiratory, thoracic and mediastinal disorders

Common: bronchitis, epistaxis, cough

Rare: nasal septum perforations

Not known: nasal irritation, dry mucous membrane, nasal congestion, sneezing, dyspnoea

Gastrointestinal disorders

Common: dyspepsia, tooth disorder

Not known: nausea

General disorders and administration site conditions

Not known: fatigue

Investigations

Not known: decreased blood cortisol.

Reduction of growth velocity has been observed in children during a post-marketing clinical trial with NASACOR T.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of NASACOR T is important. It allows continued monitoring of the benefit/risk balance of NASACOR T. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or the Pharmacovigilance Unit at CFAO at chcsa-za-safety@cfao.com.

4.9 Overdose

Like any other nasally administered corticosteroid, acute overdosing is unlikely in view of the total amount of active ingredient present. In the event that the entire contents of the bottle were administered all at once, via either oral or nasal application, clinically significant systemic adverse events would most likely not result. The patient may experience some gastrointestinal upset if taken orally.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A. 21.5.1 Corticosteroids and analogues

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use, corticosteroids

ATC code: R01 AD11.

Triamcinolone acetonide is a more potent derivative of triamcinolone, a synthetic glucocorticoid. Glucocorticoids have amongst others also anti-inflammatory action.

The precise mechanism of glucocorticoid action in allergic conditions is unknown.

5.2 Pharmacokinetic properties

Pharmacokinetic characterisation of the triamcinolone acetonide nasal spray formulation was determined in both normal subjects and in patients with allergic rhinitis.

Absorption

Single dose intranasal administration of 220 µg of triamcinolone acetonide nasal spray in normal subjects and patients demonstrated dose related absorption of triamcinolone acetonide.
The mean peak plasma concentration was approximately 0,5 ng/mL (range 0,1 to 1,0 ng/mL) and occurred at 1,5 hours post dose. The mean plasma concentration was less than 0,06 ng/ mL at 12 hours, and below the assay detection limit at 24 hours. The average terminal half-life was 3,1 hours.

Distribution and elimination

Based upon intravenous dosing of triamcinolone acetonide phosphate ester, the half-life of triamcinolone acetonide was reported to be 88 minutes. The volume of distribution (Vd) reported was 99,5 L (SD ± 27,5) and clearance was 45,2 L/hour (SD ± 9,1) for triamcinolone acetonide. The plasma half-life of corticosteroids does not correlate well with the biologic half-life.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80

Microcrystalline cellulose and carboxymethylcellulose sodium

Dextrose anhydrous

Disodium edetate

Hydrochloric acid (for pH-adjustment)

Benzalkonium chloride

Purified water

Sodium hydroxide (for pH-adjustment).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

White high density polyethylene (HDPE) bottle fitted with a metered dose spray pump unit, placed in an outer carton. Each bottle contains 16,5 g of suspension, providing 120 actuations.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CFAO Healthcare South Africa (Pty) Ltd.

Atrium on 5th, 6th Floor, Sandton City,

Corner Maude and 5" Street,

Sandton,

Gauteng, 2146

8. REGISTRATION NUMBER

29/21.5.1/0715

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12 July 1996

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23 October 2023

NAMIBIA

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