CLEAN PROPOSED PROFESSIONAL INFORMATION FOR TRIAMIST

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

TRIAMIST (Nasal Spray)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered spray delivered by the nasal actuator contains 55 µg of triamcinolone acetonide.

3. PHARMACEUTICAL FORM

White to off-white coloured homogenous redispersible suspension, free from visible foreign matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TRIAMIST nasal spray is indicated for the preventative treatment of seasonal and perennial allergic rhinitis symptoms in adults and children 6 years of age and older.

4.2. Posology and method of administration

Do not exceed the prescribed dosage. Shake the bottle well before each use.

Each actuation delivers 55 micrograms triamcinolone acetonide from the nose piece to the patient after an initial priming of 5 sprays until a fine mist is achieved. It will remain adequately primed for 2 weeks. If the product is unused for more than 2 weeks, then it can be adequately reprimed with one spray. The nozzle should be pointing away from

the patient while the patient is priming the device.

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 for adults and children 12 years and older.

Paediatric patients 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. But once symptoms are controlled, patients should be maintained on the lowest effective dose. 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, TRIAMIST nasal spray should be discontinued, and consideration to alternative 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. When the maximum benefit has been achieved and symptoms have been controlled, reducing the dose to 110 µg (one spray in each nostril once per day) has been shown to be effective in maintaining control of the allergic rhinitis symptoms in patients who were initially controlled on 220 µg/day.

Cleaning instructions

TRIAMIST should be cleaned at least once a week or more often if it gets blocked.

To clean TRIAMIST:

- Pull the nozzle upwards to detach from the bottle.
- Soak the nozzle and dust cap in warm water for a few minutes.
- Rinse the nozzle and dust cap under clean running water.
- Shake off excess water and allow to dry at room temperature before refitting onto the bottle.
- Do not use a pin or other sharp object to unblock.
- Re-fit the nozzle and dust cap.
- Prime the unit as necessary until a fine mist is produced and then use as normal.

4.3 Contraindications

TRIAMIST is contra-indicated in patients with known hypersensitivity to triamcinolone acetonide or any of the other ingredients in the formulation.

In children below the age of 6 years.

4.4 Special warnings and precautions for use

Safety and effectiveness have not been established in children below the age of 6 years. 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.

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

The replacement of a systemic corticosteroid with a topical corticoid, such as TRIAMIST nasal spray, can be accompanied by signs of adrenal insufficiency and, 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 and transferred to topical corticoids such as TRIAMIST 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.

Infections of the nose and pharynx with *Candida albicans* may occur. When such an infection develops it may require treatment with appropriate local or systemic therapy and discontinuance of treatment with TRIAMIST nasal spray.

TRIAMIST nasal spray should be used with caution, if used 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, TRIAMIST nasal spray should be used with caution until healing has occurred.

Nasal septal perforations have been reported in rare instances. When used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, TRIAMIST nasal spray should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.

4.5 Interaction with other medicines and other forms of interaction

Corticosteroids have an inhibitory effect on wound healing and should be used with caution in conjunction with TRIAMIST (see **Section 4.4**).

4.6 Fertility, pregnancy and lactation

Pregnancy

Corticosteroids have been shown to be teratogenic in animals following topical application. Therefore, TRIAMIST should not be used during pregnancy.

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

Lactation

Safety of TRIAMIST during lactation has not been established, therefore women should not breastfeed their infants.

4.7 Effects on ability to drive and use machines:

TRIAMIST 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 the mucous membranes of the nose and throat.

Nervous system disorders:

Frequent: Headache.

Eye disorders:

Less frequent: Ocular hypertension.

Respiratory, thoracic and mediastinal disorders:

Frequent:	Rhinitis and pharyngitis, burning, dryness or other irritation inside the nose
Less frequent:	Crusting inside nose or epistaxis, sore throat, ulceration of nasal mucosa, nasal candidiasis, pharyngeal candidiasis, nasal septal perforation, burning or stinging continuing after use of spray, as well as sneezing and sinus congestion, stuffy nose and throat discomfort.
Frequency unknown:	Dry mucous membrane

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 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

In the event of the entire contents of the bottle being administered all at once, either via oral or nasal application. The patient may experience some gastrointestinal upset. Overdosage should be treated symptomatically and supportively.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A 21.5.1 Corticosteroids and analogues.

ATC code: R 01 AD

Mechanism of action

Triamcinolone acetonide is a derivative of triamcinolone, a synthetic glucocorticoid. Glucocorticoids have anti-inflammatory action, amongst others. The precise mechanism of glucocorticoid action in allergic conditions is unknown.

5.2 Pharmacokinetics properties

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

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

(V_d) 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 biological half-life.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Anhydrous glucose
- Benzalkonium chloride 10 % *m/v* solution 0,015 % *m/m*
- Carboxymethyl cellulose
- Disodium edetate
- Hydrochloric acid (for pH-adjustment)
- Microcrystalline cellulose
- Polysorbate 80
- Sodium hydroxide (for pH-adjustment)
- Water for injection.

6.2 Incompatibilities

None known**.**

6.3 Shelf life

The shelf life of TRIAMIST is 24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light.

Discard within two months after first opening the bottle.

6.5 Nature and contents of container

20 mL cylindrical white opaque HDPE bottle providing 120 actuations with a net fill weight of 16,5 g. Each bottle is fitted with a white metered nasal pump, white opaque nasal actuator and a translucent dust cap for nozzle.

The bottle is packed in a carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

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Parc du Cap

Mispel Street

Bellville 7530

Customer care: 080 222 6662

8. REGISTRATION NUMBER(S)

45/21.5.1/0676

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 October 2015

10. DATE OF REVISION OF THE TEXT

31 August 2023