

CLEAN PROPOSED PATIENT INFORMATION LEAFLET FOR TRIAMIST**SCHEDULING STATUS:**

S3

TRIAMIST (Nasal spray, 55 µg per spray)

Triamcinolone acetonide

Read this entire leaflet carefully before you start using TRIAMIST.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRIAMIST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRIAMIST is and what it is used for
2. What you need to know before you use TRIAMIST
3. How to use TRIAMIST
4. Possible side effects
5. How to store TRIAMIST
6. Contents of the pack and other information.

1. What TRIAMIST is and what it is used for

TRIAMIST nasal spray belongs to a class of medicines called corticosteroids. It is used for the preventative treatment of allergic conditions of the nose, known as seasonal

and perennial allergic rhinitis, which produce symptoms such as sneezing, itching, nasal stuffiness and runny nose.

2. What you need to know before you use TRIAMIST

Do not use TRIAMIST:

- If you are hypersensitive (allergic) to the active substance, triamcinolone acetonide, or to any of the other ingredients in the formulation.
- If you are under the age of 6 years.

Tell your doctor of the above before using TRIAMIST.

Warnings and precautions

Take special care with TRIAMIST:

The presence of other medical conditions may impact on the use of TRIAMIST as it may require dose adjustment or special monitoring. Please inform your doctor or pharmacist if any of the following applies to you:

- You are pregnant or breastfeeding (please see "**Pregnancy and breastfeeding**").
- You are taking corticosteroids in tablet form or per injection. Please see "**Other medicines and TRIAMIST**").
- Your immune system is suppressed.
- You have an infection of the nose or throat whether it is a viral, fungal or bacterial infection.
- You are currently receiving treatment for tuberculosis or have a history of tuberculosis.
- You were recently diagnosed with an ulcer of your nasal septum or have recently undergone nasal surgery or recently suffered trauma to your nose.

Safety and efficacy of TRIAMIST have not been established in children younger than 6 years. Oral corticosteroids (i.e. tablets or syrup) have been shown to cause growth suppression in children and teenagers, particularly if they received high doses over extended periods. If your child is on corticosteroids and you are concerned that he/she may be growing too slowly, please discuss this with the treating doctor.

TRIAMIST may cause thrush (yeast infection with *Candida albicans*) of the nose or throat. This will present with white plaques in the mouth, throat or nose. Please inform your doctor if such symptoms develop as you may require treatment with antifungal medicines and/or discontinuation of therapy with TRIAMIST.

In some instances, TRIAMIST has caused perforation of the nasal septum. This may present with nose bleeds, pain or with a nasal discharge. Please report any such symptoms to your doctor immediately.

If you use excessive doses of TRIAMIST for a prolonged period of time, you may develop systemic side-effects, such as weight gain, redistribution of body fat, thinning of the skin, and suppression of adrenal gland function, amongst others. Please use TRIAMIST exactly as instructed by your doctor.

Other medicines and TRIAMIST:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is particularly important to inform your doctor if you have recently used or are currently using other corticosteroids, such as corticosteroid tablets or injections. If TRIAMIST is combined with other corticosteroids, you will require careful monitoring

for possible side-effects. You may develop withdrawal symptoms, such as joint or muscle pain, depression, and tiredness if your dose of other corticosteroids is decreased too rapidly. This may also cause worsening of asthma symptoms. Your doctor will also monitor you for other complications, such as reduced function of your adrenal glands. If you are using very high doses of corticosteroids (to suppress the function of your immune system), you should avoid exposing yourself to people with chickenpox or measles.

Using TRIAMIST with food and drink:

TRIAMIST is not affected by food and drink.

Pregnancy and breastfeeding:

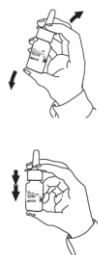
The use of TRIAMIST during pregnancy may harm your baby as studies in animals have shown that topical application of corticosteroids, such as in TRIAMIST, may be harmful. The safe use of TRIAMIST while you are breastfeeding your baby has not been established and you should not breastfeed your infant.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

Driving and using machines:

There are no effects on ability to drive or use machines.

3. How to use TRIAMIST**Directions for use:**

**Figure 1**

1. Shake the container gently, then remove the dust cap.
2. Hold the container, as shown, with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.
3. Before using TRIAMIST for the first time, or if it has not been used for a long time, shake the bottle, press several times until a fine uniform mist comes out of the nozzle.
4. Blow your nose gently.
5. Close one nostril and insert the nozzle in the other nostril, as shown. Tilt your head slightly forward, keeping the nozzle in the upright position.

**Figure 2**

6. Start to breathe in through your nose and, while breathing in, press down to release a spray.
7. Breathe out through your mouth. Repeat steps 6 and 7 if another spray is required.
8. Repeat steps 5, 6 and 7 for the other nostril.
9. Wipe the nozzle with a clean cloth, replace the dust cap and store in an upright position.

Do not share medicines prescribed for you with any other person.

Always use TRIAMIST exactly as indicated or as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with TRIAMIST will last. Do not stop treatment early because you feel better. If you have the impression that the effect of TRIAMIST is too strong or too weak, tell your doctor or pharmacist.

This medicine will not relieve your symptoms immediately. It may provide relief from the first day of treatment, but usually you will need to use it for a few days to obtain full benefit.

Shake bottle well before each use (refer to Figure 1).

Each spray from the nasal actuator delivers 55 µg of the active ingredient (triamcinolone acetonide) to the nose, after initial priming of TRIAMIST nasal spray (usually 5 sprays until a uniform spray is observed). If the nasal spray has not been used for 14 days or longer, it can be adequately reprimed with one spray. You should point the nozzle away from you when you are priming the spray (refer to Figure 2).

Do not exceed the prescribed dosage. The usual dose in adults and children 12 years and older is two sprays in each nostril once a day. For children 6 to 12 years the usual dose is one spray per nostril once a day (refer to Figure 2). In some instances your doctor may decide to decrease or increase your dose, depending on your response to treatment and/or the severity of your condition.

Most patients will experience relief of symptoms within the first three to four days of treatment. However, it may take up to three weeks to experience the full benefit of

treatment. If you have not responded to treatment with TRIAMIST after 3 weeks, your doctor may decide to stop treatment with TRIAMIST. Otherwise you should continue with treatment for as long as your doctor has instructed you. Continuous use of TRIAMIST beyond 3 months in children younger than 12 years is not recommended.

Cleaning instructions:

Your TRIAMIST nasal spray 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.

If you use more TRIAMIST than you should:

In the event that the entire contents of the bottle are administered all at once, via either the mouth or nose, clinically significant systemic adverse events may occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use TRIAMIST:

Always use TRIAMIST exactly as your doctor has instructed you. To obtain maximal

benefit from treatment, it is important to use TRIAMIST every day and not to skip doses. However, if you missed a dose and it is almost time for your next dose, skip the missed dose and return to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose.

If you stop using TRIAMIST:

TRIAMIST nasal spray should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.

4. Possible side effects

TRIAMIST can have side effects.

Not all side effects reported for TRIAMIST are included in this leaflet. Should your general health worsen while using TRIAMIST, or if you experience any untoward effects, please consult your doctor, pharmacist or other health care professional for advice.

The following side-effects have been reported frequently:

- Headache.
- Stuffed or runny nose, sore throat, and burning, dryness, or other irritation inside the nose. The latter is usually mild and transient.

The following side-effects have been reported less frequently:

- Crusting inside the nose or nose bleeds, especially if the spray is improperly aimed towards the nasal septum and not to the sides.
- Ulceration of the cells lining the nose.
- Thrush (*Candida albicans* infection) of the nose presenting with white patches inside the nose or throat.

- Perforation of the nasal septum, which may present with nose bleeding. pain or a nasal discharge.
- Burning or stinging continuing after the use of the spray.
- Sneezing.
- Sinus congestion and stuffy nose.
- Throat discomfort.
- Raised pressure inside the eye.

The incidence of the following side-effect is not known:

- Dryness of the mucous membrane (lining) inside the nose or mouth.

Reporting of side effects

If you get side effects, talk to your doctor, 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> or by e-mail:

drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of **TRIAMIST**.

5. How to store TRIAMIST

Store at or below 25 °C.

In order to protect from light, do not store in open cupboards exposed to light.

Discard within two months after first opening the bottle.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What TRIAMIST contains

The active substance is 55 µg of triamcinolone acetonide per spray.

The other ingredients are anhydrous glucose, carboxymethyl cellulose, disodium edetate, hydrochloric acid (for pH-adjustment), microcrystalline cellulose, polysorbate 80, sodium hydroxide (for pH-adjustment) and water for injection.

The preservative is benzalkonium chloride 10 % m/v solution 0,015 % m/m.

What TRIAMIST looks like and contents of the pack

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

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.

Holder of Certificate of Registration

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