DATA SHEET

1 TELNASE (55 MICROGRAMS/DOSE NASAL SPRAY SUSPENSION)

Telnase 55 microgram/dose nasal spray suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triamcinolone acetonide.

Each 20mL bottle of Telnase contains 16.5g of suspension with 9.075mg triamcinolone acetonide, and provides at least 120 actuations, each delivering 55 micrograms triamcinolone acetonide from the nose piece to the patient, after an initial priming of five sprays.

Excipients with known effect: benzalkonium chloride

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray suspension.

Telnase is supplied as an unscented, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium, contained in a white 20mL high density polyethylene (HDPE) bottle, fitted with a metered-dose spray pump unit containing triamcinolone acetonide.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Telnase is indicated for the treatment and prophylaxis of seasonal and perennial allergic rhinitis in adults and children over 6 years of age.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dose

Adults and children aged 12 years and over

The recommended starting dose is 220 micrograms, as two sprays in each nostril once daily. Once symptoms are controlled, patients may be maintained on 110 micrograms, as one spray in each nostril, once daily.

Paediatic Population

Children aged 6 to 12 years

The maximum recommended dose is 110 micrograms, as one spray in each nostril, once daily. In patients with more severe symptoms, a dose of 220 micrograms may be used. Once symptoms are controlled patients should be maintained on the lowest effective dose.

Children under 6 years of age

The safety and efficacy of Telnase in children under 6 years of age have not been established, therefore use in this group of patients is currently not recommended.

Method of Administration and Instructions for Use/Handling

Telnase is for nasal administration only, and should be used regularly for optimal efficacy.

Each bottle of Telnase provides at least 120 actuations after an initial priming of five sprays. Each actuation delivers 55 microgram triamcinolone acetonide from the nose piece to the patient, after initial priming of five sprays.

Telnase will remain adequately primed for two weeks. If the product is unused for more than two weeks, then it can be reprimed with one spray.

It is important to shake the bottle gently before each use.

In some patients an improvement of symptoms may be apparent within the first day of treatment. However, several days of treatment may be needed for optimal benefit to be achieved.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Care must be taken when transferring patients from systemic steroid treatment to Telnase, due to the possibility of impaired adrenal function. Patients previously treated for prolonged periods with systemic corticosteroids prior to transfer to topical corticosteroids, such as Telnase, should be carefully monitored for acute adrenal insufficiency in response to stress.

If Telnase is prescribed for patients already using corticosteroids, the dosage of Telnase should be included when determining the total daily dosage of corticosteroid.

When Telnase is given at excessive doses, or when given concurrently with corticosteroid treatment including inhaled glucocorticoids, systemic corticosteroid effects may occur. 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).

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

Caution is also required if Telnase is administered to patients having untreated fungal, bacterial or systemic viral infections, or ocular herpes simplex.

Because of the inhibitory effect of corticosteroids on wound healing, Telnase should be used with caution in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, until healing has occurred.

Growth retardation has been reported in children receiving nasal corticosteroids, including Telnase 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. In addition, consideration should be given to referring the patient to a paediatric specialist. The long-term effects of reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height are unknown.

Visual disturbance may be associated 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). Close monitoring is warranted in patients with a history of increased intraocular pressure, glaucoma, and/or cataracts.

This medicine contains 15 micrograms of benzalkonium chloride in each actuation of Telnase. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

Drug interactions have not been systematically studied between Telnase and other drugs administered intranasally or drugs administered by other routes. However, no interactions are known to date.

4.6 FERTILITY, PREGNANCY AND LACTATION

Pregnancy (Category B3)

Clinical experience with Telnase in pregnant women is limited, but in animal studies corticosteroids including triamcinolone acetonide have been shown to induce teratogenic effects. Therefore Telnase should not be administered during pregnancy unless the therapeutic benefit to the mother is considered to outweigh the potential risk to the foetus.

Infants born to mothers who have received substantial doses of corticosteroids should be carefully observed for hypoadrenalism.

Breast-Feeding

Triamcinolone acetonide may, like other corticosteroids, pass into human breast milk. Therefore Telnase should not be administered to nursing women unless the therapeutic benefit to the mother is considered to outweigh the potential risk to the baby.

Fertility

No studies on the effects on human fertility have been conducted. See section 5.3.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Telnase has no known effect on the ability to drive or operate machines.

4.8 UNDESIRABLE EFFECTS

The following frequency rating has been used, when applicable:

Very common ≥ 10 %; Common ≥1 and <10 %; Uncommon ≥0.1 and < 1 %; Rare ≥0.01 and < 0.1 %; Very rare < 0.01 %.

The overall incidence of adverse events reported in clinical trials with Telnase was generally very low, and most commonly involved the mucous membranes of the nose and throat.

The most frequent adverse effects in adults and children 6 years and over were:

- Nervous system disorders
  Common: headache
- Respiratory, thoracic and mediastinal disorders
  Common: Epistaxis, cough, bronchitis, dyspepsia
- Infections and infestations
  Common: Rhinitis, pharyngitis, Flu syndrome
- Gastrointestinal disorders
  Common: Tooth Disorder

Postmarketing

The following additional adverse effects have been reported during post-marketing experience; they are derived from spontaneous reports and therefore, the frequency of these adverse reactions is not known: nasal irritation, dry mucous membrane, nasal congestion, sneezing, alterations of taste and smell, nausea, insomnia, dizziness, fatigue, dyspnoea, decreased blood cortisol, blurred vision, increased ocular pressure, cataract, glaucoma, chorioretinopathy, pruritus, rash, and hypersensitivity.

As with other nasally administered corticosteroids, nasal septal perforations have been reported in rare instances.

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

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. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 OVERDOSE

Like any other nasally administered corticosteroid, acute overdosing with Telnase 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 be most unlikely. The patient may experience some gastrointestinal upset if taken orally.

If overdosage is suspected, treatment should be supportive and directed towards control of the relevant symptoms.

Chronic usage at excessive doses may lead to the appearance of systemic corticosteroid effects such as hypercorticism and adrenal suppression. If such changes occur, Telnase should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

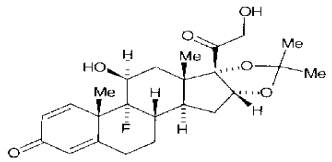
5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use, Corticosteroids, ATC code: R 01 AD11

Triamcinolone acetonide, a corticosteroid, is a white or cream-coloured, almost odourless, crystalline powder. It is practically insoluble in water; sparingly soluble in alcohol, in chloroform, or in methyl alcohol; very slightly soluble in ether.

Triamcinolone acetonide has a molecular weight of 434.51. Telnase has a target pH of 5.0 within a range 4.5 - 6.0.

Chemical structure:



Chemical name: 9α-fluoro-11β,21-dihydroxy-16α, 17α -isopropylidenedioxypregna-1,4-diene-3,20-dione ($C_{24}H_{31}FO_6$).

CAS number : 76-25-5

Mechanism of Action

Triamcinolone acetonide is a more potent derivative of triamcinolone, and is approximately eight times more potent than prednisone in animal models of inflammation.

Although the precise mechanism of corticosteroid antiallergic action is unknown, corticosteroids are clinically effective in the treatment of allergic diseases.

Clinical Efficacy and Safety

Clinical trials in adults and children over 12 years of age with seasonal or perennial allergic rhinitis have demonstrated that Telnase, at a dose of 220 micrograms per day, provides statistically significant relief of nasal symptoms including sneezing, stuffiness, discharge and itching, when compared with placebo. The safety and efficacy of Telnase has also been adequately studied in children aged 6 to 12 years. Statistically significant reductions in the severity of nasal symptoms of allergic rhinitis were demonstrated at doses of 110 or 220 micrograms per day.

Telnase does not have an immediate effect on allergic signs and symptoms. An improvement in some patient symptoms may be apparent within the first day of treatment and relief may be expected in three to four days. If Telnase is prematurely discontinued, symptoms may not recur for several days.

In clinical studies performed in adults and children at doses of triamcinolone acetonide up to 440 microgram per day intranasally, no suppression of the Hypothalamic-Pituitary-Adrenal (HPA) axis has been observed.

5.2 PHARMACOKINETIC PROPERTIES

Single dose intranasal administration of 220 micrograms of triamcinolone acetonide in normal adult subjects and in adult patients with allergic rhinitis, demonstrated low absorption of triamcinolone acetonide.

The mean peak plasma concentration was approximately 0.5ng/mL (range 0.1 to 1.0ng/mL) and occurred at 1.5 hours post-dosing. The mean plasma drug concentration was less than 0.06ng/mL at 12 hours and below the assay detection limit at 24 hours. The average terminal half-life was 3.1 hours.

Dose proportionality was demonstrated in both patients and healthy volunteers following a single intranasal dose of 110 or 220 micrograms of Telnase. Following multiple (440 micrograms/day) doses in paediatric patients, plasma drug concentrations, AUC, C_{max} and T_{max} were similar to those values observed in adult patients.

Three metabolites of triamcinolone acetonide have been identified in human plasma: 6β-hydroxytriamcinolone acetonide, 21-carboxytriamcinolone acetonide, and 21-carboxy-6β-hydroxy triamcinolone acetonide. All three metabolites are without significant pharmacological activity relative to the parent compound.

5.3 PRECLINICAL SAFETY DATA

In pre-clinical studies, only effects typical of glucocorticoids were observed.

No evidence of mutagenicity was detected from *in vitro* tests (a reverse mutation test in Salmonella bacteria and a forward mutation test in Chinese hamster ovary cells), and studies in rodents have shown no treatment-related carcinogenicity of triamcinolone acetonide.

Like other corticosteroids, triamcinolone acetonide has been shown to be teratogenic in animals, resulting (in rats and rabbits) in cleft palate and/or internal hydrocephaly and axial skeletal defects. Other teratogenic effects including CNS and cranial malformations have been observed in non-human primates.

No genotoxicity studies have been conducted with triamcinolone acetonide. However, other members of this chemical class were not genotoxins.

Triamcinolone acetonide was not carcinogenic in mice and rats when administered at oral doses of 3µg/kg/day and 1µg/kg/day, respectively, for 2 years. Another two year carcinogenicity study in Sprague Dawley rats given triamcinolone acetonide (4.8µg/kg/day), budesonide (50µg/kg/day) or prednisolone (368µg/kg/day) in the drinking water found an increased incidence of hepatic tumours. These findings suggest that these tumours are a class effect and are probably due to corticosteroid activity.

Triamcinolone acetonide caused increased foetal resorptions, stillbirths, decreased pup weight and survival rate in rodents but no changes in pregnancy rates.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Microcrystalline cellulose
Carmellose sodium
Polysorbate 80
Anhydrous glucose
Benzalkonium chloride
Disodium edetate
Purified water
Hydrochloric acid
Sodium hydroxide

6.2 INCOMPATIBILITIES

None known.

6.3 SHELF LIFE

Telnase has a shelf-life of 24 months. The shelf-life after the bottle is first used is two months.

The bottle should be discarded after 120 actuations have been delivered or no later than two months after first use.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

20mL white high density (HDPE) bottle, fitted with a metered-dose spray pump unit.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

Any unused medicine or waste material should be disposed of in accordance with local requirements

7 MEDICINE SCHEDULE

Pharmacy Only Medicine

8 SPONSOR

Distributed by:

sanofi-aventis new zealand limited
Level 8,
56 Cawley Street
Ellerslie
Auckland

Telephone: (09) 580 1810

9 DATE OF FIRST APPROVAL

25 February 1999

10 DATE OF REVISION OF THE TEXT

7 December 2017

SUMMARY OF CHANGES

Section	Summary of Change
All	Format change to align with Medsafe data sheet format.
1	Editorial changes
2	Addition of excipient with known effect
4.2	Editorial changes
4.3	Contraindication reworded for clarity
4.4	Expanded warning on visual disturbances; Additional warning on excipient benzalkonium chloride
4.6	Addition of Fertility Section
4.8	Additional adverse events; Addition of reporting of suspected adverse reactions section
4.9	Addition of National Poisons Centre phone number
5.1	Addition of ATC code; Editorial changes
6.1	Align excipients in INN; Editorial changes
6.4	Removal of Keep out of reach of children statement
6.5	Expanded container information
6.6	Addition of section
8	Editorial changes