

Data Sheet

Telnase®

Name of Medicine

Triamcinolone acetonide

Presentation

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.

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.

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.

Telnase also contains microcrystalline cellulose and carmellose sodium, polysorbate 80, anhydrous glucose, benzalkonium chloride, edetate disodium, purified water, hydrochloride acid and sodium hydroxide.

Uses

Actions

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 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.

Pharmacokinetics

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: 6 β -hydroxytriamcinolone acetonide, 21-carboxytriamcinolone acetonide, and 21-carboxy-6 β -hydroxy triamcinolone acetonide. All three metabolites are without significant pharmacological activity relative to the parent compound.

Indications

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

Dosage and Administration

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

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.

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.

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.

Contraindications

Telnase is contraindicated in patients with known hypersensitivity to any constituents of the formulation.

Warnings and Precautions

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.

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.

Pregnancy and Lactation

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.

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.

Effects on Ability to Drive and Use Machines

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

Other

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.

Adverse Effects

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 events considered to be at least possibly drug-related were rhinitis, headache, pharyngitis, epistaxis, nasal irritation, dry mucous membrane, nasal congestion and sneezing. Only epistaxis occurred consistently more frequently in Telnase-treated adult patients than placebo-treated patients, but this effect was mild and transient.

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

Interactions

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.

Overdosage

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.

Pharmaceutical Precautions

Instructions for Use/Handling

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.

Incompatibilities

None known.

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.

Special Precautions for Storage

Store below 25°C. Keep out of reach of children.

Medicine Classification

Pharmacy Only Medicine

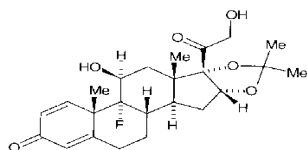
Package Quantities

20mL bottle.

Further Information

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: 9 α -fluoro-11 β ,21-dihydroxy-16 α , 17 α -isopropylidenedioxypregna-1,4-diene-3,20-dione (C₂₄H₃₁FO₆).

CAS number : 76-25-5

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