

Trispray®

Triamcinolone Acetonide BP

Metered Dose Nasal Spray

COMPOSITION

Trispray® (Triamcinolone Acetonide) is a metered dose manual pump spray, containing microcrystalline suspension of Triamcinolone Acetonide BP providing 120 metered doses. Each actuation delivers 55 mcg of Triamcinolone Acetonide BP.

PHARMACOLOGY

Triamcinolone Acetonide is a more potent derivative of Triamcinolone and is approximately 8 times more potent than prednisone. Although the precise mechanism of action of corticosteroid antiallergic action is unknown, corticosteroids are very effective in the treatment of allergic diseases. When given by intranasal spray, Triamcinolone Acetonide provides relief from allergy-induced watery nasal discharge (rhinorrhoea), nasal congestion, postnasal drip, sneezing, and itching of the back of the throat.

INDICATION

Trispray® is indicated for the treatment and prophylaxis of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

DOSAGE AND ADMINISTRATION

Adults and children 12 years of age and older : The recommended dose is 220 mcg as 2 sprays in each nostril once daily. Once symptoms are controlled patients can be maintained on 110 mcg (1 spray in each nostril once daily). The minimum effective dose should be used to ensure continued control of symptoms.

Children 6 to 12 years : The recommended dose is 110 mcg as 1 spray in each nostril once daily. If required, 220 mcg (2 sprays in each nostril) once daily.

Children 2 to 5 years : The recommended dose is 110 mcg as 1 spray in each nostril once daily.

Trispray® Nasal Spray is not recommended for children under 2 years of age.

CONTRAINDICATION

No specific contraindications but caution is required in patients with hypersensitivity to any constituents of the formulation.

ADVERSE REACTIONS

The most commonly reported adverse reactions in clinical trials with Triamcinolone Acetonide included those involving mucous membranes of the nose & throat. The most prevalent adverse reactions considered are rhinitis, headache, & pharyngitis. The nasopharyngeal adverse effects included epistaxis, nasal irritation, dry mucous membrane,

DRUG INTERACTION

None is known.

PRECAUTION AND WARNING

If there is any reason to suppose that adrenal function is impaired, care must be taken while transferring patients from systemic steroid treatment to Triamcinolone. In clinical studies with Triamcinolone administered intranasally, the development of localized infections, on the nose, and pharynx with *Candida albicans*, has rarely occurred. When such an infection develops it may require treatment with appropriate local therapy and discontinuance of treatment with Triamcinolone.

USE IN PREGNANCY AND LACTATION

There is no adequate and well controlled studies in pregnant women with Triamcinolone. Because animal studies indicate a teratogenic effect, Triamcinolone should be used during pregnancy if the potential benefit justifies the potential benefit to fetus. It is not known whether Triamcinolone is excreted in human breast milk.

STORAGE CONDITION

Store below 30° C. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Trispray®: Each bottle contains Triamcinolone Acetonide aqueous suspension adequate for 120 metered doses.

Manufactured by

