Trispray®
Triamcinolone Acetonide
Intranasal corticosteroid

COMPOSITION

Trispray $^{\circ}$ (Triamcinolone Acetonide) is a metered dose manual pump spray, containing microcrystalline suspension of Triamcinolone Acetonide BP providing 120 metered doses. Each actuation delivers 55 μ gm 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 antiallergenic action is unknown, corticosteroids are very effective in the treatment of allergic diseases in man. When given by intranasal spray, Triamcinolone Acetonide provides relief from allergy-induced watery nasal discharge (rhinorrhea), 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 6 years of age and older.

DOSAGE AND ADMINISTRATION

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

Pediatric Patients aged 6 to 12 years: The recommended dose is 110 μ gm as 1 spray in each nostril once daily.

Trispray ® spray is not recommended for children under 6 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 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,

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Trispray®

naso-sinus congestion and sneezing although these are seen as frequently with placebo. As with other nasally inhaled corticosteroids, nasal septal perforation has been reported.

OVERDOSE

Like any other nasally administered corticosteroid, acute overdosing with Trispray® is unlikely in view of the total amount of active ingredient present.

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

USE IN PREGNANCY AND LACTATION

There are 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 at a temperature not exceeding 25° C Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Trispray * : Amber bottle containing Triamcinolone Acetonide aqueous suspension adequate for 120 metered doses.



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