

1.6.3 Patient Information leaflet (PIL)

DESCRIPTION :

Triamcinolone acetonide is a long-acting depot preparation of triamcinolone, a potent synthetic corticosteroid with marked anti-inflammatory action. It is a 9 α - derivative of Prednisolone designated as (C₂₁H₂₆FO₆ = 434.5).

COMPOSITION :

Triamcinolone acetonide 40mg/ml water for injection q.s.

PHARMACOLOGICAL ACTIONS :

Triamcinolone has highly selective glucocorticoid activity without significant mineralocorticoid action. As a part of glucocorticoid activity it also possesses pronounced anti-inflammatory property that forms the basis of most of its therapeutic uses. It is a long acting agent with duration of action of several hours. In contrast, the acetonide ester of triamcinolone has actions lasting for several days to weeks.

THERAPEUTIC INDICATIONS :

Intravitreal Triamcinolone acetonide has been used for various ocular diseases. Severe chronic allergic and inflammatory processes involving the eye, such as herpes zoster ophthalmicus, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, sympathetic ophthalmia, diffuse diabetic macular edema, chronic cystoid macular edema, prevention of PVR, identification of vitreous during vitrectomy in patients with rhegmatogenous retinal detachment, macular edema secondary to CRVO & BRVO, chronic uveitis, pars planitis, diabetic

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pseudoptosis, vitreous hemorrhage, corticosteroid induced ocular hypertension, post injection infectious endophthalmitis, sterile Endophthalmitis, retinal lesions by the injection needle etc.

DOSAGE :

The normal dose of 4 mg / 0.1 ml may be sufficient for intravitreal injection in any case related to uveitis or retinal problem. For uvea related inflammation the normal dose of PST (Posterior Subtenon injection) 20 mg / 0.5 ml is recommended. However the maximum dose that can be administered is 40 mg / 1 ml per dose.

ADMINISTRATION :

Before use shake the vial well to ensure a uniform suspension. Rule out clumping or granular appearance of the suspension before withdrawing into syringe. After withdrawal inject without delay to avoid setting in the syringe. Use fresh sterile hypodermic 27 gauge needle 1inch or more in length to inject Auorcort.

PRESENTATION :

Vial containing 40 mg / ml as a sterile aqueous suspension with pack of five.

STORAGE :

Store below 30°C.

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papillopathy, uveitic cystoid macular edema, serous retinal detachment in Vogt-Koyanagi-Harada syndrome, exudative age related macular degeneration, chronic prephthical ocular hypotony, persistent pseudophakic cystoid macular edema, ocular Ischemic syndrome etc.

CONTRAINDICATIONS :

Contraindicated in those persons who have intra ocular infections like corneal ulcer, patients having glaucoma.

WARNINGS AND PRECAUTIONS :

1. Being a suspension this preparation should not be injected intravenously.
2. It should be injected only under strict aseptic and antiseptic precautions.
3. It is not recommended for children under 6 years of age.
4. Risk of hypoadrenalism in infants if given to nursing mothers or infants.
5. Immunization procedures should not be undertaken during steroid therapy.
6. Intraoperative triamcinolone injection may obscure visualization intraoperatively & postoperatively in eyes with hydrophilic acrylic lenses.

ADVERSE EFFECTS :

Mild iritis, mild vitritis, retinal & choroid vascular occlusion, pain on injection, corneal ulceration due to improper site of injection, swelling, cataract, elevation of IOP.

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Instructions for use leaflet

Aurocort™
(Triamcinolone acetonide 40mg/ml)
PRESERVATIVE FREE



Intravitreal / Intraocular use only
NOT FOR INTRAVENOUS OR INTRADERMAL USE

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