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1.4 Quality Information Summary

Enclosed

1.5 Product Information

1.5.1 Summary of Product characteristics.
AUROCORT (Triamcinolone Acetonide Injection BP 40mg/ml)

1. Name of the medicinal product
AUROCORT.

2. Qualitative and quantitative composition
Each ml contains,

Triamcinolone Acetonide	BP	40mg
Water for injection		q.s

3. Pharmaceutical form
Intraocular injection
Sterile white colour suspension

4. Clinical particulars
4.1 Therapeutic indications

Triamcinolone acetonide injectable suspension is indicated for visualization during vitrectomy.

4.2 Posology and method of administration

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.

4.3 Contraindications

The presence of active or suspected ocular or periocular infections. Patients with systemic fungal infections.

4.4 Special warnings and precautions for use

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.

4.5 Interaction with other medicinal products and other forms of interaction

Overview
Specific interaction studies have not been conducted

Drug-Drug Interactions
Specific drug interaction studies have not been conducted

Drug-Food Interactions
Interactions with food have not been established.

Drug-Herb Interactions
Interactions with herbal products have not been established.

Drug-Laboratory Interactions
Interactions with laboratory tests have not been established.

4.6 Pregnancy and lactation

Pregnant Women:
There are no data from the use in pregnant women. Studies in animals with systemic triamcinolone at doses below the recommended humanintravitreal dose have shown reproductive toxicity. Prolonged or repeated systemic corticoid useduring pregnancy has been associated with an increased risk of intra-uterine growth retardationandfetal adrenal suppression. Although systemic exposure of triamcinolone would be expected to be very low after intravitreal administration, triamcinolone is not recommended for use during pregnancy.

Nursing Women:
It is unknown whether is excreted in human milk. Although systemic exposure of triamcinolone is expected to be very low after intravitreal administration, a risk to the sucklingchild cannot be excluded. A decision should be made whether to discontinue breast-feeding or toavoid, taking into account the benefit of breast-feeding for the child andthe benefit of therapy for the mother.

Pediatrics (< 18 years of age):

Is not recommended for use in children or adolescents. The efficacy and safety Pediatric patients have not been established.

Geriatrics (> 65 years of age):

No overall differences in safety and effectiveness have been observed between elderly and other adult patients.

4.7 Effects on ability to drive and use machines

There is no specific requirement is required.

4.8 Undesirable effects/Adverse effects

Eye Disorders

Conjunctivitis allergic
Vitreous hemorrhage
Hyphema
Punctate keratitis
Retinal artery occlusion
Visual acuity reduced

Gastrointestinal disorders
Abdominal discomfort
Cheilitis
Constipation

General disorders and administration site conditions
Feeling abnormal

4.9 Overdose

No information provided.

5. Pharmacological properties
5.1 Pharmacodynamic properties

Clinical Pharmacology:

Following intravitreal injection, dispersal of water-insoluble triamcinolone acetonide particles within the vitreous chamber provides contrast to the transparent vitreous humor and membranes.

Pharmacodynamics

Triamcinolone acetonide is a glucocorticosteroid that has been used as an anti-inflammatory agent for the treatment of various ocular diseases. Following intravitreal injection, water insoluble

particles of triamcinolone acetonide disperse within the vitreous chamber, providing contrast between the transparent vitreous humor and membranes.

5.2 Pharmacokinetic properties

The systemic exposure of triamcinolone acetonide following intravitreal injection of
was evaluated in a subset (n = 22) of the 32 enrolled patients in Study C-08-055.Triamcinolone acetonide plasma concentrations were minimal as reflected by quantifiable concentrations in only 2 of the 22 patients 3 hours post-injection. Triamcinolone acetonide plasma concentrations for these two patients were 0.828 ng/mL and 0.583 ng/mL and barely exceeded the lower limit of quantitation (0.5 ng/mL). These findings are consistent with results reported in literature where triamcinolone acetonide was only measurable in 2 of 20 patients administered a single high dose (20 to 25 mg) intravitreal injection of triamcinolone acetonide
(Degenring 2004). The maximum triamcinolone acetonide plasma concentration observed afterintravitreal injection (approximately 0.8 ng/mL) is approximately 13-fold less than that observedafter oral administration (10.5 ng/mL).

5.3 Preclinical safety data

Not known.

6. Pharmaceutical particulars

6.1 List of excipients

Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf life

24months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Triamcinolone acetonide injectable suspension 40 mg/mL forms a milky white suspension when shaken. It is supplied as 1 mL of a 40 mg/mL sterile suspension in a flint Type 1 single use glass vial with a grey rubber stopper and an open target seal. 5Vials/carton is packaged inside a cardboard carton.

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6.6 Special precautions for disposal and other handling
There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Aurolab, No.1, Sivagangai Main road, Veerapanjan, Madurai - 625020, India**.**

8. Marketing authorisation number(s)
TN 00002387

9. Date of renewal of the authorisation
30.10.2020

10. Date of revision of the text
Not Applicable