

1.6 Product Information

1.6.1 Summary of Product characteristics.

AUROMIDE PLUS(Tropicamide 0.8% w/v and Phenylephrine Hcl 5% w/v Eye Drops)

1. Name of the medicinal product

AUROMIDE PLUS

2. Qualitative and quantitative composition

Tropicamide 0.8% w/v and Phenylephrine Hcl 5% w/v Eye Drops

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, solution.

Clear colorless aqueous solution.

4. Clinical particulars

4.1 Therapeutic indications

It is indicated for cataract surgery to obtain Mydriasis.

4.2 Posology and method of administration

Adults (including the elderly):

1 drop followed by a second drop after an interval of 5 minutes. A further 1 drop may be instilled after 30 minutes, if required.

Children:

At the discretion of the physician.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to Tropicamide and Phenylephrine Hydrochloride. Tropicamide is contraindicated in narrow angle glaucoma and in eyes where the filtration angle is narrow, as an acute attack of angle closure glaucoma may be precipitated.

Hyperthyroidism

4.4 Special warnings and precautions for use

Use with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Care should be exercised in small children.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

Tropicamide may cause increased intraocular pressure. The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients. Determine the intraocular pressure and anastomosis of the depth of the angle of the anterior chamber prior to initiation of therapy.

Using with Phenylephrine Hydrochloride:

1. Coronary diseases
2. Advanced arteriosclerosis
3. Bradycardia
4. Partial heart block
5. Myocardial diseases
6. Atherosclerosis
7. Hypertension
8. Nasal and ophthalmic form use cautiously in type-1 diabetes mellitus

4.5 Interaction with other medicinal products and other forms of interaction

Phenylephrine may interact with systemically administered MAOIs.

4.6 Pregnancy and lactation

There is no evidence as to the drug's safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. This product should only be used in pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Patient warning: Patients who receive a mydriatic may suffer from photophobia and this may impair their ability to drive under certain circumstances.

4.8 Undesirable effects

Transient stinging, dry mouth and blurred vision may occur following the use of this product.

4.9 Overdose

Systemic effects from Tropicamide are not expected. Should an overdose occur causing local effects, e.g. sustained mydriasis, pilocarpine or 0.25% w/v physostigmine should be applied.

Discontinue the drug and give supportive and symptomatic treatment. Closely monitor vital signs.

Use atropine sulfate to block reflex Bradycardia. Treat excessive hypertension with phentolamine. Treat

cardiac arrhythmia with propranolol. Treat excessive mydriatic effect with levodopa.

5. Pharmacological properties.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: MYDRIATICS and CYCLOPLEGICS, Tropicamide combinations, ATC code: S01FA56.

Auromide Plus which combines two synthetic mydriatic agents (tropicamide - anticholinergic, and phenylephrine - alpha sympathomimetic)

Mechanism of action:

Phenylephrine is a direct acting sympathomimetic agent. It causes mydriasis via the stimulation of alpha-adrenergic receptors of the pupillary dilator (the resulting contraction of the pupillary dilator causes pupil dilation). There is almost no cycloplegic effect.

Tropicamide is a parasympatholytic agent, which acts by binding to and blocking the M4 muscarinic receptors of the eye muscles. It prevents the iris sphincter muscle and ciliary body muscle from responding to cholinergic stimulation, producing dilation of the pupil and paralysis of the ciliary muscle (cyclopegia).

Pharmacodynamic effects of Tropicamide

Tropicamide is a parasympatholytic agent, which acts by blocking the action of the parasympathetic nervous system. As acetylcholine is the neuro-humoral transmitter at the receptor site of the parasympathetic nervous system, tropicamide competes with acetylcholine for uptake at the receptor sites, thereby blocking its action. The results are mydriasis, due to unopposed action of the dilator pupillae, and cyclopegia.

Pharmacodynamic effects of Phenylephrine

Maximal mydriasis occurs in 60- 90 minutes with recovery after 5 - 7 hours.

The mydriatic effects of phenylephrine can be reversed with thymoxamine.

5.2 Pharmacokinetic properties

Tropicamide

No data on the pharmacokinetics of topical tropicamide are available.

Phenylephrine

Absorption

Phenylephrine is a weak base at physiological pH. The extent of ocular penetration is determined by the condition of the cornea. A healthy cornea presents a physical barrier, in addition to which, some metabolic activity may occur. Where the corneal epithelium is damaged, the effect of the barrier and the extent of metabolism are reduced, leading to greater absorption

5.3 Preclinical safety data

Not known

6. Pharmaceutical particulars

6.1 List of excipients

Sodium metabisulphite BP

Ascorbic acid BP

Sodium citrate Dihydrate BP

EDTA disodium BP

Hydroxyl propyl methyl cellulose USP

Chlorobutanol BP

Purified water BP

6.2 Incompatibilities

None known

6.3 Shelf life

24months unopened.

Discard 28 days after first opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Packed in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a mon carton with package insert.

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)

TN00002387

9. Date of first authorisation/renewal of the authorisation

2022

10. Date of revision of the text

Not Applicable