Summary of Product Characteristics

1. Name of the medicinal product :

ONAMIDE PLUS

Tropicamide & Phenylephrine HCl Ophthalmic Solution

2. Qualitative and Quantitative composition:

Composition:

Tropicamide USP	0.8% w/v
Phenylephrine Hydrochloride USP	5.0% w/v
Benzalkonium Chloride Solution USP	0.02% w/v
(As preservative)	
Sterile aqueous base	q.s.

3. Pharmaceutical Form:

Eye Drops

Description: A clear and colourless solution filled in 5 ml LDPE vials.

4. Clinical Particulars:

4.1 Therapeutic indications

As a mydriatic, Tropicamide and Phenylephrine is indicated in some pre & post-operative states and for ophthalmologic examinations like during ophthalmoscopy, slit-lump examination, retinal photography, laser treatment or adjunct in the treatment of anterior uveitis. It also may be used in temporary lowering of intraocular pressure in glaucoma.

4.2 Posology and method of administration

Instill 1-2 drops in the eye (s) 15-20 minutes before examination. If examination is not conducted within 20-30 minutes, an additional drop may be placed in the eye(s) to prolong the effect.

4.3 Contraindications

Known hypersensitivity to any ingredient of the preparation, & narrow angle glaucoma.

4.4 Special warnings and precautions for use

For external use only.

Not for injection.

Do not touch the nozzle tip or other dispensing tip to any surface, since this may contaminate the solution.

Do not use after the expiry date on the pack.

4.5 Interaction with other medicinal products and other forms of interaction

Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine or ophthalmic cholinesterase inhibitors.

4.6 Fertility, pregnancy and lactation

Pregnancy Category C

Tropicamide should be given to pregnant women only if clearly needed. It is not known whether tropicamide is excreted in human milk. Caution should need when tropicamide is administrated to a nursing woman.

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

Ocular side effects include transient stinging & raised intra-ocular pressure. On prolonged administration local irritation, hyperemia odema & conjunctivitis may occur. Systemic effects include arrhythmias, hypertension, & coronary artery spasm.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Dilation of the pupils with loss of accommodation & photophobia. Increased intra-ocular pressure.

5. Pharmacological properties

Pharmacotherapeutic group: Mydriatics and Cycloplegics

ATC code: S01FA56

Mechanism of action

Onamide Plus is an ophthalmic solution which combines two synthetic mydriatic agents (phenylephrine, alpha sympathomimetic, and tropicamide, anticholinergic).

Phenylephrine is a direct acting sympathomimetic agent. It causes mydriasis via the stimulation of alpha receptors. There is almost no cycloplegic effect.

Tropicamide is an anticholinergic which blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation thus dilating the pupil (mydriasis). At higher concentrations (1%), tropicamide also paralyses accommodation. This preparation acts rapidly and has a relatively short duration of action.

5.1 Pharmacodynamic properties

Maximal mydriasis occurs in 60- 90 minutes with recovery after 5 - 7 hours. The mydriatic effects of phenylephrine can be reversed with thymoxamine.

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5.2 Pharmacokinetic properties

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.

Tropicamide administered topically to the human eye does not bind to tissues as firmly as does atropine. The wash out time for half recovery of carbachol responsiveness was shown to be less than 15 minutes for non-pigmented iris and 30 minutes for pigmented iris.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium Chloride Solution

Hydrochloric Acid

Sodium Hydroxide Pellets (Inj.)

Water for Injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

Use the solution within one month after opening the container.

6.4 Special precautions for storage

Do not store above 30°C. Protect from direct sunlight.

6.5 Nature and contents of container

5 ml LDPE bottle in a carton along with insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.1 Marketing Authorization Holder:

DAWA LIMITED

PLOT NO. 7879/8, BABA DOGO ROAD,

P. O. BOX 16633-00620, NAIROBI, KENYA.

7.2 Manufacturer:

THETA PHARMACEUTICALS LIMITED

D-42, IIE SIDCUL, SELAQUI, DEHRADUN-248011,

UTTARAKHAND, INDIA

8. Marketing Authorization Number:

CTD12641

9. Date of first Authorization /renewal of the authorization:

October 2025

10. Date of revision of text:

20/11/2025

11. Dosimetry (if applicable)

N/A

12. Instructions for preparation of radiopharmaceuticals:

Not applicable