SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:
Proprietary name: Tobrasone-D Eye Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Tobramycin Sulfate USP
Eq. to Tobramycin 0.3% w/v
Dexamethasone Sodium Phosphate BP
Eq. to Dexamethasone Phosphate 0.1% w/v
Benzalkonium Chloride Solution BP 0.02% w/v
(As preservative)
Sterile aqueous vehicle q.s.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:
Eye drops, Solution.
Clear, colourless Solution filled in sterile vial

4. CLINICAL PARTICULARS:
4.1 Therapeutic indications:
This medication is used to treat or prevent eye infections. This medication contains two drugs. Tobramycin belongs to a class of drugs called aminoglycoside antibiotics. It works by stopping the growth of bacteria. Dexamethasone belongs to a class of drugs called corticosteroids. It works by reducing swelling.
This medication treats/prevents only bacterial eye infections. It will not work for other types of eye infections. Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

4.2 Posology and method of administration:
To apply eye drops, wash your hands first. To avoid contamination, do not touch the dropper tip or let it touch your eye or any other surface. Shake the bottle well before each dose.
Adults: One drop instilled into the conjunctival sac every 4-6 hours while patient is awake. During the initial 24-48 hours, the dosage may be increased to one drop every two hours while patient is awake. Dosing should continue for 14 days not to exceed a maximum of 24 days.
If you are using mother kind of eye medication (e.g., drops or ointments), wait at least 5 to 10 minutes before applying other medications. Use eye drops before eye ointments to allow the eye drops to enter the eye.
Use this medication regularly in order to get the most benefit from it. Remember to use it at the same times each day. Continue to use this medication for the full time prescribed, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection.
Inform your doctor if your condition persists or worsens.

Method of administration:
For ophthalmic use only.

4.3 Contraindications:
It is contraindicated individuals who are hypersensitive to it any components of Tobrasone-D

eye drops. This drug is not prescribed if you have allergic symptoms and also for children.

4.4 Special warnings and precautions for use:
Contact lens use: This product contains the preservative Benzalkonium chloride, which may cause eye irritation. Remove contact lens prior to administration and wait for 15 min before installation.
Before using Tobrasone-D eye drops tell your doctor or pharmacist if you are allergic to either drug; or to other aminoglycoside antibiotics (e.g., gentamicin); or if you have any other allergies. This product may contain inactive ingredients (such as preservatives like Benzalkonium chloride), which can cause allergic reactions or other problems. Talk to your pharmacist for more details.
Before using this medication, tell your doctor or pharmacist your medical history, especially of other eye problems (e.g., glaucoma).
Your vision may be temporarily unstable after applying this drug. Do not drive, use machinery, or do any activity that requires clear vision until you are sure you can perform such activities safely. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.
It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding.

4.5 Interaction with other medicinal products and other forms of interaction:
Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop, or change the dosage of any medicine before checking with them first.
Before using this medication, tell your doctor or pharmacist of all prescription and non-prescription/herbal products you may use.
Keep a list of all your medications with you and share the list with your doctor and pharmacist.

4.6 Pregnancy and Lactation:
Pregnancy
Tobrasone-D eye drops may use during pregnancy; no human data available, though risk of fetal hams not expected based on expected limited systemic absorption
Lactation
Tobrasone-D eye drops may use while breastfeeding; no human data available, though risk of infant hams and adverse effects on milk production not expected based on limited maternal systemic absorption

4.7 Effects on ability to drive or use machines:
TOBRASONE-D has no or negligible influence on the ability to drive and use machines.
No studies on the effects on the ability to drive and use machines have been performed. As with any eye drop, temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

4.8 Undesirable Effects
The most commonly reported side-effects of Tobrasone-D are eye redness, eye discomfort, eyelid itching/swelling.
Use of this medication for prolonged/repeated periods may result in a new fungal eye infection and may increase your risk for other eye problems (e.g., glaucoma, cataracts). Do not use this medication for longer than prescribed. Tell your doctor right away if you notice any of the

following: new or worsening eye symptoms (e.g., discharge, swelling), vision changes, eye pain.
A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. 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:
Tobrasone-D may be harmful if swallowed. If someone has overdosed and has serious symptoms such as passing out or trouble breathing, please go to the emergency department of the closest hospital or nursing home.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic Properties:
Pharmacotherapeutic group: Anti-inflammatory agents and anti-infectives in combination, corticosteroids and anti-infectives in combination.

Tobramycin:
Tobramycin is a potent, broad-spectrum, rapidly bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome. Tobramycin in this combination provides antibacterial protection against susceptible bacteria. The following MIC breakpoints, separating susceptible from intermediate susceptible organisms, and intermediate susceptible from resistant organisms, are suggested: S (< 4 µg/ml, R (> 8 µg/ml). The prevalence of resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable. The following information gives only an approximate guidance on probabilities whether bacteria will be susceptible to tobramycin in Tobrasone-D.
The breakpoint definitions classifying isolates as susceptible m resistant are useful in predicting clinical efficacy of antibiotics that are administered systemically. However, when the antibiotic is administered in very high concentrations topically directly on the site of infection, these breakpoint definitions may not be applicable. Most isolates that would be classified as resistant by systemic breakpoints are indeed successfully treated topically.

Dexamethasone:
The efficacy of corticosteroids for the treatment of inflammatory conditions of the eye is well established. Corticosteroids achieve their anti-inflammatory effects through suppression of vascular endothelial cell adhesion molecules, cyclooxygenase I or II, and cytokine expression. This action culminates in a reduced expression of pro-inflammatory mediators and the suppression of adhesion of circulating leukocytes to the vascular endothelium, thereby preventing their migration into inflamed ocular tissue. Dexamethasone has marked anti-inflammatory activity with reduced mineralocorticoid activity compared with some other steroids, and is one of the most potent anti-inflammatory agents.

5.2 Pharmacokinetic Properties:
Tobramycin:
Animal studies have shown that tobramycin is absorbed into the cornea following ocular administration. Following systemic administration to patients with normal renal function, a plasma half-life of approximately 2 hours has been observed. Tobramycin is eliminated almost exclusively by glomerular filtration with little if any biotransformation. Plasma concentrations of tobramycin following the 2-day topical ocular regimen of TOBRASONE-D were below the limit of quantification in most subjects or low (≤0.25 microgram/ml).

Dexamethasone:
Following ocular administration, dexamethasone is absorbed into the eye with maximum concentrations in the cornea and aqueous humour attained within 1-2 hours. The plasma half-life of dexamethasone is approximately 3 hours. Dexamethasone is eliminated extensively as metabolites. Systemic exposure to dexamethasone is low following topical ocular administration of TOBRASONE-D. Peak dexamethasone plasma levels after the last topical dose ranged from 220 to 888pg/ml (mean 555 ± 217pg/ml) after administration of one drop of TOBRASONE-D to each eye four times per day for two consecutive days.

5.3 Preclinical Safety Data:
Non-clinical data revealed no special hazard for humans from topical ocular exposure to tobramycin or dexamethasone based on conventional repeated-dose topical ocular toxicity studies, genotoxicity or carcinogenicity studies. Effects in non-clinical reproductive and developmental studies with tobramycin and dexamethasone were observed only at exposures considered sufficiently in excess of the maximum human ocular dosage indicating little relevance to clinical use for low-dose short-term courses of therapy.
Tobramycin has not been shown to induce teratogenicity in rats or rabbits. The ocular administration of 0.1% dexamethasone resulted in fetal anomalies in rabbits. Dexamethasone had no adverse effects on female fertility in a chorionic gonadotropin primed rat model.

6. PHARMACEUTICAL PARTICULARS:
6.1 List of Excipients:
Borax
Boric acid
Sodium chloride
Sodium Metabisulphite
Propylene Glycol
Tween-80
Benzalkonium chloride solution.

6.2 Incompatibilities:
Not applicable.

6.3 Shelf Life:
24 months.
Discard the bottle 28 days after first opening.

6.4 Special Precautions for storage:
Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:
White Plastic Vial. Each pack contains 1 bottle of 5ml with Pack Insert.

6.6 Special precautions for disposal and other handling:
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder and manufacturing site addresses: --

Marketing authorization holder:
GALAXY PHARMACEUTICAL LTD
P.O. Box 39107-00623, Nairobi, Kenya

Manufacturing site address:
Hanuchem Laboratories
Plot No. 13, Industrial Area, Sector-5,
Parwanoo, Distt. Solon-173220 (H.P) India.

8. Marketing authorization number:
CTD10084
9. Date of first authorization /renewal of the authorization:
29/07/2026

10. Date of revision of text:
29/07/2026