SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TOBREX® (tobramycin ophthalmic ointment) 0.3%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of TOBREX® solution contains: **Active:** tobramycin 0.3% (3mg).
Preservative: chlorobutanol 0.5%. Inactives: mineral oil, white petrolatum.

Tobramycin is a water-soluble aminoglycoside antibiotic, the ointment is a non-aqueous ophthalmic ointment active against a wide variety of gram-negative and gram-positive ophthalmic pathogens.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.

Clear, colourless ointment.

4. CLINICAL PARTICULARS

In Vitro Data: In vitro studies have demonstrated tobramycin is active against susceptible strains of the following microorganisms: Staphylococci, including S. aureus and S. epidermidis (coagulase-positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some Streptococcus pneumoniae.

Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii, most Proteus vulgaris strains, Haemophilus influenzae and H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus and some Neisseria species. Bacterial susceptibility studies demonstrate that in some cases, microorganisms resistant to gentamicin retain susceptibility to tobramycin.

4.1 Therapeutic indications

TOBREX® (tobramycin ophthalmic ointment) 0.3 % is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of TOBREX (tobramycin ophthalmic ointment) 0.3%. Clinical studies have shown tobramycin to be safe and effective for use in children.

4.2 Posology and method of administration

Paediatric population

Safety and effectiveness in pediatric patients below the age of 2 months has not been established.

Method of administration

For ocular use.

How to Apply TOBREX (tobramycin ophthalmic ointment) 0.3%:
1. Tilt your head back.
2. Place a finger on your cheek just under your eye and gently pull down until a "V" pocket is formed between your eyeball and your lower lid.
3. Place a small amount (about ½ inch) of TOBREX® (tobramycin ophthalmic ointment) 0.3% in the "V" pocket. Do not let the tip of the tube touch your eye. 4. Look downward before closing your eye.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart.

Patients must be instructed to remove soft contact lenses prior to application of and wait 15 minutes after instillation of the dose before reinsertion.

4.3 Contraindications

TOBREX (tobramycin ophthalmic ointment) 0.3 % is contraindicated in patients with known hypersensitivity to any of its components.

4.4 Special warnings and precautions for use

Geriatric Use: No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

Patients must be instructed to remove contact lenses prior to application of Tobrex and wait 15 minutes after instillation of the dose before reinsertion.

4.5 Fertility, pregnancy and lactation

Pregnancy

Reproduction studies in three types of animals at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Breast-feeding

Because of the potential for adverse reactions in nursing infants from TOBREX® (tobramycin ophthalmic ointment) 0.3%, a decision should be made whether to discontinue nursing the infant or discontinue the drug, taking into account the importance of the drug to the mother.

Fertility

There are no data on the effects of Tobrex on human fertility.

4.6 Undesirable effects

The most frequent adverse reactions to TOBREX (tobramycin ophthalmic ointment) 0.3% are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than three of 100 patients treated with TOBREX® (tobramycin ophthalmic ointment) 0.3%.

Additional adverse reactions identified from postmarketing use include anaphylactic reaction, Stevens-Johnson syndrome, and erythema multiforme. The following additional adverse reactions have been reported with systemic aminoglycosides: Neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients

receiving systemic aminoglycoside therapy. Aminoglycosides may aggravate muscle weakness in patients with known or suspected neuromuscular disorders, such as myasthenia gravis or Parkinson's disease, because of their potential effect on neuromuscular function

4.7 Overdose

A topical overdose with Tobrex is not likely to occur or to be associated with toxicity.

5 PHARMACEUTICAL PARTICULARS

5.1 List of excipients

chlorobutanol 0.5%
mineral oil,
white petrolatum.

5.2 Incompatibilities

Not applicable.

5.3 Shelf life

2 years.

Discard 4 weeks after first opening.

5.4 Special precautions for storage

Do not store above 25°C.

5.5 Nature and contents of container

3.5g sterile ophthalmic ointment in an aluminum tube with a white polyethylene tip and white polyethylene cap.

Pack size of 1 tube.
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5.6 Special precautions for disposal

No special requirements.

6 MARKETING AUTHORISATION HOLDER

Novartis Nigeria Limited

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Plot 52-54 Isaac John Street

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7 MARKETING AUTHORISATION NUMBER(S)

A4-1975

8 DATE OF REVISION OF THE TEXT

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