SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OFTAMYCIN-DX 0.3% + 0.1% Eye Drops, Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 mL

Active substance:

Tobramycin ..... 3 mg

Dexamethasone* ..... 1 mg

1 mg of dexamethasone equivalent to 1.32 mg of dexamethasone sodium phosphate

Excipient(s):

Benzalkonium chloride ..... 0.1 mg

See Section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Sterile eye drops

A clear, colorless solution free of particles.

4. CLINICAL CHARACTERISTICS

4.1 Therapeutic indications

In cases of inflammatory ocular conditions responsive to steroids, where a corticosteroid is indicated, or where there is a risk of superficial bacterial infection or bacterial ocular infection (e.g., inflammatory conditions affecting the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye; chronic anterior uveitis; and corneal injuries or foreign body penetration resulting from chemical, radiation, or thermal burns).

It is also used for the treatment of inflammation and for infection prophylaxis following cataract surgery.

4.2 Posology and method of administration

Administered to the eye.

Posology/frequency and duration of administration:

One or two drops are instilled into the conjunctival sac every four to six hours. During the first 24 to 48 hours, the dose may be increased to one or two drops every two hours. If clinical symptoms improve, the frequency is gradually reduced. Care should be taken not to discontinue treatment prematurely.

In severe cases, one or two drops are instilled every hour until inflammation is controlled; over the next 3 days, the frequency is gradually reduced to one or two drops every two hours; then,

for 5 to 8 days, one or two drops are instilled every 4 hours; and finally, if deemed necessary, one or two drops are instilled once daily for the last 5 to 8 days.

Following cataract surgery, the dosage is one drop four times daily starting from the day after surgery and continuing for up to 24 days. Treatment may be initiated the day before surgery with one drop four times daily, and continued after surgery with one drop, then four times daily for up to 23 days. If necessary, the frequency may be increased to one drop every two hours during the first two days of treatment.

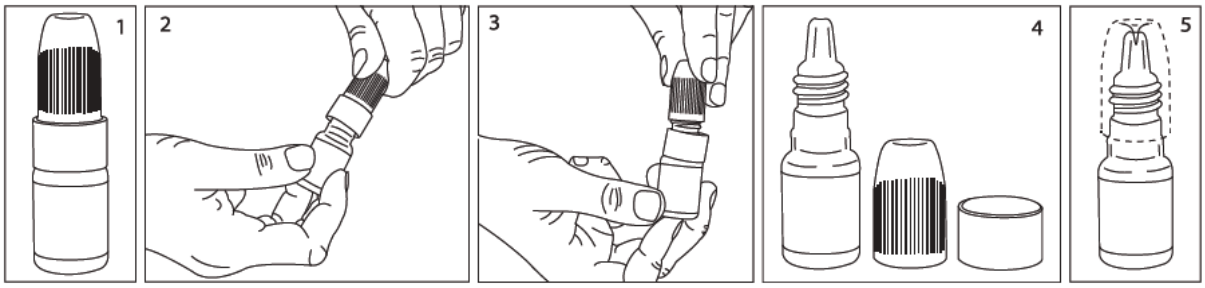
Regular monitoring of intraocular pressure is recommended.

Method of Administration:
Shake the bottle well before use.

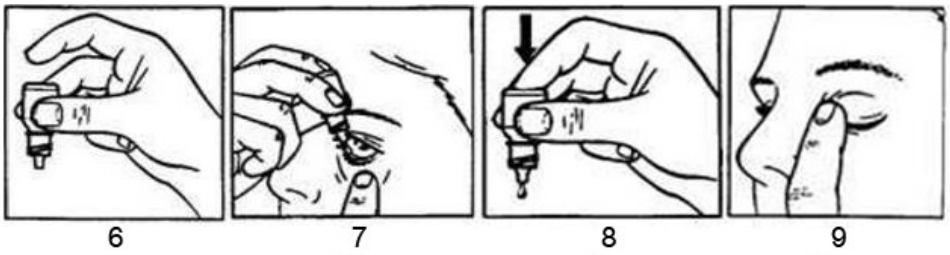
For ophthalmic use only. OFTAMYCIN-DX is administered by instilling into the eye; it is not injected into the eye.

To prevent contamination, care should be taken to ensure that the dropper tip and the solution do not come into contact with the eyelid, the surrounding area, or other surfaces.

After instillation, it is recommended to gently close the eyelid and occlude the nasolacrimal duct. This measure may reduce systemic absorption of the medicated product administered via the ocular route and help minimize systemic side effects.



- The patient should take the bottle of OFTAMYCIN-DX and a mirror.
- The patient should wash their hands.
- Open the bottle cap.
- They should remove the ring located under the cap (see Figure 3 and Figure 4).
- The cap should be closed again without the ring. The plastic pin inside the cap will pierce the tip of the bottle (see Figure 5).



1. The cap should be opened.
2. Hold the bottle downward between your thumb and index finger (Figure 6).
3. The patient should tilt their head back. They should pull the lower eyelid down with a clean finger until a ‘pocket’ forms between the eye and the eyelid. The drops will flow into this pocket (Figure 7).
4. Bring the tip of the bottle close to the eye. Use a mirror if necessary.
5. The dropper should not touch the eye, eyelid, the area around the eye, or other surfaces. This may affect the drops.
6. Light pressure from the index finger on the inverted bottle will release one drop of OFTAMYCIN-DX at a time (Figure 8).
7. After using OFTAMYCIN-DX, the lower eyelid should be released, the eye should be closed, and the inner corner of the eye near the nose should be gently pressed with a finger (Figure 9). This prevents OFTAMYCIN-DX from draining out.
8. If the drops are being administered to both eyes, the same steps should be repeated for the other eye.
9. The bottle cap must be tightly closed immediately after use.

If the drop does not reach the eye, the patient should try again.

When used in combination with other topical ophthalmic medicinal products, a 5-minute interval should be observed between consecutive applications.

Additional information on specific populations:
Renal/Hepatic impairment:
OFTAMYCIN-DX has not been studied in these patient populations. However, since systemic absorption of dexamethasone and tobramycin following topical application is low, no dose adjustment is necessary.

Pediatric population:
Not indicated for use in pediatric patients. (See Section 4.4.)

There are no safety and efficacy data available for children under 2 years of age treated for 7 days for bacterial external ocular inflammation.

The use of OFTAMYCIN-DX in infants and young children is not recommended unless absolutely necessary.

The possibility of use in pediatric patients requiring cataract surgery may be considered.

Geriatric population:
No special dose adjustment is required in the elderly.

4.3 Contraindications

- In cases of hypersensitivity to tobramycin, dexamethasone, or any of the excipients listed in Section 6.1,
- In cases of epithelial herpes simplex keratitis (dendritic keratitis), smallpox, chickenpox, and other viral diseases of the cornea and conjunctiva,
- Mycobacterial eye infections caused by acid-fast bacilli such as *Mycobacterium tuberculosis, Mycobacterium leprae*, or *Mycobacterium avium*, but not limited to these,
- Fungal diseases of the ocular structures,
- It is contraindicated in cases of untreated inflammatory infections of the eye.

4.4 Special warnings and precautions for use
For topical ophthalmic use only. Do not inject into the eye.

Prolonged use (longer than the maximum duration used in clinical trials [24 days]) or increased frequency of application may result in ocular hypertension/glaucoma and the formation of posterior subcapsular cataracts, leading to damage to the optic nerve and a decrease in visual acuity and visual field. Visual disturbances may be reported with the use of systemic and topical corticosteroids. If the patient experiences symptoms such as blurred vision or other visual disturbances, the patient should be referred to an ophthalmologist for evaluation of rare conditions such as cataracts, glaucoma, or central serous chorioretinopathy (CSCR) reported following the use of systemic and topical corticosteroids. In susceptible patients, increased intraocular pressure may occur even at standard doses. Intraocular pressure in patients receiving long-term corticosteroid therapy should be monitored regularly and frequently. This is important because the risk of corticosteroid-induced ocular hypertension is particularly higher in children and tends to manifest earlier than in adults. OFTAMYCIN-DX is not approved for use in pediatric patients.

The risk of developing corticosteroid-induced increased intraocular pressure and/or cataracts is higher in patients predisposed to these conditions (e.g., diabetic patients).

Cushing's syndrome and/or adrenal suppression associated with systemic absorption of ocular dexamethasone may occur following intensive or prolonged uninterrupted treatment in

susceptible patients, including those treated with CYP3A4 inhibitors (including ritonavir and cobicistat) and children. In such cases, treatment should be tapered off gradually.

Cross-reactions with other aminoglycosides may occur, and it should be considered that patients sensitive to topical ocular tobramycin may also be sensitive to other topical and/or systemic aminoglycosides.

Serious adverse reactions, including neurotoxicity, ototoxicity, and nephrotoxicity, have been observed in patients receiving systemic tobramycin therapy. Caution should be exercised if used concomitantly.

In cases of refractory corneal ulcers where steroid therapy is used, the possibility of fungal infection should be considered. If a fungal infection develops, steroid therapy should be discontinued. As with other antibiotics, prolonged use of tobramycin may result in overgrowth of organisms resistant to treatment, including fungi. If superinfection occurs, appropriate treatment should be initiated immediately.

Long-term use may also lead to secondary ocular infections due to suppression of the host cell response. Corticosteroids may reduce resistance to bacterial, viral, fungal, or parasitic infections, contribute to their development, and mask the clinical symptoms of infection.

Secondary bacterial ocular infections may also occur following suppression of the immune response. Treatment with corticosteroid medications may conceal or exacerbate acute inflammatory infections of the eye. In conditions causing thinning of the cornea or sclera, perforation has been reported to occur with the use of topical steroids.

In some patients, sensitivity to topically applied aminoglycosides may occur. The severity of sensitivity may vary from local effects to systemic reactions (e.g., erythema, itching, urticaria, skin rash, anaphylactic reactions, or bullous reactions). If a hypersensitivity reaction occurs, use of the product should be discontinued.

Topical corticosteroids applied to the eye may delay corneal wound healing.
Topical nonsteroidal anti-inflammatory drugs (NSAIDs) are known to have a slowing and delaying effect on healing. The combined use of topical NSAIDs and topical steroid medications may increase the risk of potential healing complications. It is known that the use of topical corticosteroids in conditions causing thinning of the cornea or sclera has been associated with perforations.

Patients should be advised not to wear contact lenses while they have an ocular infection. Since OFTAMYCIN-DX eye drops contain benzalkonium chloride as a preservative, they may cause irritation and are known to discolor soft contact lenses. Therefore, patients should be advised

to remove their contact lenses before applying OFTAMYCIN-DX and to wait 15 minutes after instilling the drops before reinserting their contact lenses.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant use with topical NSAIDs and topical steroid medications may increase the risk of potential healing complications. Plasma concentrations of dexamethasone may increase in patients treated with ritonavir (see Section 4.4).

CYP3A4 inhibitors (including ritonavir and cobicistat): By reducing dexamethasone clearance, these may result in increased effects and adrenal suppression/Cushing's syndrome. The combination should be avoided unless the benefits outweigh the risk of increased systemic corticosteroid side effects; if used, patients should be monitored for systemic corticosteroid effects.

Additional information on specific populations:

Pediatric population:

No interaction studies have been conducted in the pediatric population.

4.6 Pregnancy and lactation

General recommendation

Pregnancy Category: C

Women of childbearing potential/Contraception

There are insufficient data regarding the use of the tobramycin/dexamethasone combination in pregnant women. Women of childbearing potential must use effective contraception during treatment.

Pregnancy

There is insufficient data on the use of the tobramycin/dexamethasone combination in pregnant women.

Animal studies are insufficient regarding effects on pregnancy and/or embryonic/fetal development and/or labor and/or postnatal development (See Section 5.3). The potential risk to humans is unknown.

OFTAMYCIN-DX should not be used during pregnancy unless absolutely necessary. It should only be used during pregnancy if the potential benefit outweighs the potential fetal risk.

A study involving aminoglycosides (including tobramycin) administered orally and parenterally to pregnant women has shown no detectable fetal risk. However, if aminoglycosides are taken during pregnancy, the possibility of their crossing the placenta or

affecting the fetus or newborns should be considered. Although there is no definitive evidence that aminoglycosides are teratogenic, ototoxic, or nephrotoxic in the fetus, the possibility of these effects should be assumed. Prolonged or repeated use of corticosteroids during pregnancy has been associated with an increased risk of intrauterine growth restriction. Newborns of pregnant women who have used corticosteroids in significant doses during pregnancy should be closely monitored for signs of hypoadrenalism.

Lactation
Systemically administered corticosteroids pass into human milk and may suppress growth, interfere with endogenous corticosteroid production, or cause other adverse effects. It is unknown whether topical application of corticosteroids provides sufficient systemic absorption to produce detectable levels in human milk. OFTAMYCIN-DX should not be used during breastfeeding unless the potential benefits outweigh the potential risks.

Fertility
No studies have been conducted to evaluate the effects of tobramycin on human or animal fertility. Clinical data on the effects of dexamethasone on male or female fertility are limited. Dexamethasone did not have an adverse effect on fertility in a rat model following prior administration of chorionic gonadotropin.

4.7 Effects on the ability to drive and use machines
OFTAMYCIN-DX has no significant effect on the ability to drive or operate machinery. As with other eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or operate machinery. If blurred vision develops after instillation of the medication, the patient should wait until vision clears before driving or operating machinery.

4.8 Undesirable effects
In clinical studies involving over 1,600 patients, the tobramycin/dexamethasone combination was administered up to 6 times daily. In these clinical studies, no serious ophthalmic or systemic adverse reactions related to the tobramycin/dexamethasone combination or its excipients were reported. The most commonly reported adverse effects associated with the tobramycin/dexamethasone combination are eye pain, increased intraocular pressure, eye irritation (burning sensation after instillation), and eye itching (occurring in less than 1% of patients).

The following adverse reactions have been reported during clinical trials and post-marketing experience with the tobramycin/dexamethasone combination. Adverse effects are classified as very common (≥1/10), common (≥1/100 to ≤ 1/10), uncommon (≥1/1,000 to ≤ 1/100), rare (≥1/10,000 to ≤ 1/1,000), very rare (≤ 1/10,000), and not known (cannot be estimated from available data).

Immune system disorders:
Not known: Hypersensitivity, anaphylactic reactions

Nervous system disorders:
Uncommon: Headache
Not known: Dizziness

Eye disorders:
Uncommon: Eye pain, ocular itching, ocular discomfort (temporary burning or stinging after instillation), ocular hypertension, conjunctival edema, increased intraocular pressure, eye irritation
Rare: Keratitis, eye allergy, blurred vision (see Section 4.4), dry eye, ocular hyperemia
Not known: Eyelid edema, eyelid erythema, mydriasis, increased tear production

Endocrine disorders:
Not known: Adrenal suppression, Cushing's syndrome (see Section 4.4)

Respiratory, thoracic disorders, and mediastinal diseases:
Uncommon: Rhinorrhea, laryngospasm

Gastrointestinal disorders:
Rare: Taste disorder (dysgeusia)
Not known: Nausea, abdominal discomfort

Skin and subcutaneous tissue disorders:
Not known: Rash, facial swelling, erythema multiforme, pruritus

Description of Selected Adverse Reactions
The adverse reactions listed below have been observed following the use of dexamethasone ophthalmic suspension:

System-organ class	Frequency	Adverse reaction
Nervous system disorders	Common	Headache
Eye disorders	Common	Eye irritation*, ocular hyperemia*, eyelid erythema, abnormal sensation in the eye*
Respiratory, chest, and mediastinal disorders	Common	Postnasal drip

The following adverse reactions have been observed following the use of tobramycin ophthalmic suspension:

System-Organ Class	Frequency	Adverse reaction
Eye disorders	Common	Ocular hyperemia, eye pain
	Uncommon	Eye itching*, ocular discomfort*, eye allergy, eyelid edema*, conjunctivitis*, photophobia, increased tearing*, keratitis*

*These adverse reactions have been observed during the postmarketing period of the tobramycin/dexamethasone combination.

Long-term use of topical ophthalmic corticosteroids may result in optic nerve damage, increased intraocular pressure, decreased visual acuity, visual field defects, the development of posterior subcapsular cataracts, and delayed wound healing.

Due to the corticosteroid component, there is an increased risk of perforation in conditions causing thinning of the cornea or sclera, particularly following prolonged treatment (see Section 4.4).

Secondary infections have developed following the use of combinations containing corticosteroids and antimicrobials. Fungal corneal infections are particularly prone to developing incidentally with long-term steroid use.

Serious adverse reactions, including neurotoxicity, ototoxicity, and nephrotoxicity, have been observed in patients receiving systemic tobramycin therapy.

Sensitivity to topically applied aminoglycosides may also be observed in some patients.

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 asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

Due to the nature of this product, no toxic effects are expected in the event of an overdose (even if the contents of the bottle are accidentally ingested). The clinically significant signs and symptoms of an OFTAMYCIN-DX overdose (punctate keratitis, erythema, increased tearing, edema, and itching of the eyelid) may resemble the adverse reaction effects observed in some patients. Topical overdose of OFTAMYCIN-DX can be managed by rinsing the eyes with lukewarm water.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmic preparations—anti-inflammatory and anti-infective combinations; corticosteroid and anti-infective combinations.
ATC code: S01CA01

Dexamethasone:
The efficacy of corticosteroids in the treatment of inflammatory conditions of the eye has been established. Corticosteroids exert their anti-inflammatory effects by suppressing vascular endothelial cell adhesion molecules, cyclooxygenase I or II, and cytokine expression. This effect results in a reduction in pro-inflammatory mediators and the suppression of leukocyte adhesion to the vascular endothelium, thereby preventing their accumulation in inflamed ocular tissue. Dexamethasone is one of the most potent anti-inflammatory agents, exhibiting a pronounced anti-inflammatory effect with less mineralocorticoid activity compared to some other steroids.

Tobramycin:
Tobramycin is a potent, broad-spectrum, rapidly bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting the assembly and synthesis of polypeptides at the ribosome. In this formulation, tobramycin provides antibacterial protection against susceptible bacteria.

The following MIC breakpoints are assumed to distinguish susceptible organisms from moderately susceptible organisms, and moderately susceptible organisms from resistant organisms: S (≤ 4 mcg/mL), R (≥ 8 mcg/mL): Resistance prevalence may vary geographically and over time for specific species, and local information regarding resistance is particularly recommended for the treatment of serious infections. In situations where the local prevalence of resistance is such that the efficacy of the agent may be questioned, at least for certain types of infections, expert advice should be sought when necessary. The following information provides only a general guide regarding the likelihood of bacterial susceptibility to tobramycin in the tobramycin/dexamethasone combination.
Breakpoint definitions used to classify isolates as susceptible or resistant are useful for predicting the clinical efficacy of systemically administered antibiotics. However, when antibiotics are applied topically at very high concentrations directly to the site of infection, these breakpoints may not be valid. Most isolates classified as resistant based on systemic breakpoints are, in fact, successfully treated topically.

In vitro studies have shown that tobramycin is active against most genera of common ocular pathogens and common skin flora bacteria listed in the Table below.

Categories	**Frequency of Acquired Resistance in**

	Europe
SENSITIVE SPECIES	
Aerobic Gram-Positive Microorganisms	
Corynebacterium species	0–3%
Methicillin-sensitive Staphylococcus aureus	0–3%
Staphylococcus epidermidis Methicillin-S[a]	0–28%
Other coagulase-negative staphylococci	0–40 %
Aerobic Gram-Negative Microorganisms	
Acinetobacter species	0 %
Citrobacter species	0 %
Escherichia coli	0%
Enterobacter species	0%
Haemophilus influenzae	0%
Klebsiella species	0%
Moraxella species	0%
Proteus species	0%
Pseudomonas aeruginosa	0%
MODERATELY SENSITIVE STRAINS (*In vitro*, moderate susceptibility)	
Aerobic Gram-Negative Microorganisms	
Serratia marcescens	
NATURALLY RESISTANT ORGANISMS	
Aerobic Gram-Positive Microorganisms	
Enterococcus species	
Methicillin-resistant Staphylococcus aureus	
Staphylococcus epidermidis Methicillin-resistant	50–70%
Streptococcus pneumoniae	30–40%
Streptococcus species	
Aerobic Gram-Negative Microorganisms	
Burkholderia cepacia	
Stenotrophomonas maltophilia	
Anaerobic Microorganisms	
Obligate anaerobic bacteria	
Others	
Chlamydia species	
Mycoplasma species	
Rickettsia species	

[a] Methicillin-susceptible (S), methicillin-resistant (R). The beta-lactam (i.e., methicillin; penicillin) resistance phenotype is not associated with the aminoglycoside resistance phenotype, and neither is associated with the virulence phenotype. Some methicillin-resistant (R) *S. aureus* strains (MRSA) are susceptible to tobramycin (MIC: S ≤ 4); conversely, some methicillin-susceptible (S) *S. aureus* strains (MSSA) are resistant to tobramycin (MIC: S ≥ 8).

The prevalence of methicillin resistance (R) can reach up to 50% of all staphylococci in some European countries.

Pediatric Population:
The safety and efficacy of the tobramycin/dexamethasone combination in children have been established through extensive clinical experience; however, only limited data are available. In a clinical study using the tobramycin/dexamethasone combination for the treatment of bacterial conjunctivitis, 29 pediatric patients aged 1 to 17 years were treated with 1 or 2 drops of the tobramycin/dexamethasone combination every 4 to 6 hours for 5 to 7 days. In this study, no differences in the safety profile were observed between adult and pediatric patients.

Additional information:
Cross-resistance between aminoglycosides such as gentamicin and tobramycin depends on the specificity of the modifying enzymes adenyltransferase (ANT) and acetyltransferase (ACC). However, cross-resistance among aminoglycoside antibiotics varies depending on the differing specificities of various modifying enzymes. The most common mechanism of acquired resistance to aminoglycosides is the inactivation of the antibiotic by modifying enzymes encoded by plasmids and transposons.

5.2 Pharmacokinetic properties

General properties

Tobramycin is a white or off-white powder that is readily soluble in water and practically insoluble in organic solvents such as chloroform and ether.

Dexamethasone is a white or off-white, crystalline powder that is practically insoluble in water.

Tobramycin:
Studies in animals have shown that tobramycin is absorbed through the cornea following ocular application. Following systemic administration in 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 minimal biotransformation, if any. Following a 2-day topical ocular tobramycin/dexamethasone combination regimen, plasma concentrations of tobramycin were below the limit of detection or at low levels (≤0.25 micrograms/mL) in most volunteers.

Dexamethasone:
Following ocular administration, dexamethasone is absorbed into the eye, reaching maximum concentrations in the cornea and aqueous humor within 1–2 hours. The plasma half-life of dexamethasone is approximately 3 hours. Dexamethasone is extensively eliminated as

metabolites. Systemic exposure to dexamethasone is low following topical ocular administration of the tobramycin/dexamethasone combination. Peak plasma levels of dexamethasone following the last topical dose ranged from 220 to 888 pg/mL (mean 555 ± 217 pg/mL) after administration of one drop of tobramycin/dexamethasone to each eye four times daily for two consecutive days.

Linearity/Non-linearity:
Ocular or systemic exposure with increasing tobramycin dose concentrations following topical ocular application of tobramycin has not been tested. Therefore, linearity of exposure with topical ocular dose could not be determined. The mean C_{max} for dexamethasone at a topical ocular dose concentration of 0.033% with 0.3% tobramycin appeared to be approximately 25 ng/mL lower than that of tobramycin/dexamethasone; however, this decrease was not proportional to the dose.

Characteristics of the patients
Renal/hepatic impairment
The pharmacokinetics of tobramycin and dexamethasone have not been studied in these patient groups.

Pediatric population
Aminoglycosides, including topical ocular tobramycin, have been widely used to treat serious Gram-negative infections in children, infants, and newborns. The clinical pharmacology of tobramycin in children has been established following systemic administration.

Following intravenous dosing, the pharmacokinetics of dexamethasone in pediatric patients appear to be similar to those in adults.

Geriatric population
No clinically significant differences in safety or efficacy have been observed between adults and the elderly.

5.3 Preclinical safety data
Nonclinical data, based on conventional repeated-dose topical ocular toxicity studies, genotoxicity, or carcinogenicity studies, indicate that topical ocular exposure to tobramycin or dexamethasone does not pose a specific risk to humans. Effects observed in non-clinical reproductive and developmental studies with tobramycin and dexamethasone were noted only at exposure levels considered sufficiently higher than the maximum human ocular dose and have little clinical relevance for short-term treatment regimens at low doses.

Tobramycin has not been shown to cause teratogenicity in rats or rabbits. Topical application of 0.1% dexamethasone caused fetal anomalies in rabbits. Dexamethasone has no adverse effect on female fertility in a rat model treated with chorionic gonadotropin.

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Benzalkonium chloride
Tyloxapol
Sodium chloride
Anhydrous sodium sulfate
Boric acid
Sodium hydroxide (for pH adjustment)
Sulfuric acid (for pH adjustment)
Injection water

6.2 Incompatibilities

Not applicable. No specific studies have been conducted regarding incompatibility.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at room temperature below 25°C. Do not refrigerate.
Once opened, the bottle must be used within 28 days.
Store the bottle in an upright position. Close the bottle tightly after use.

6.5 Nature and contents of container

A dropper-tipped inner stopper, a 5 mL white low-density polyethylene (LDPE) bottle, and a white screw-on cap are used.

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. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

2018/28

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization : 23.01.2018
Renewal of the authorization :

10. DATE OF REVISION OF THE TEXT