

**COLIRCUSÍ Gentamicin (gentamicin 0.3%)**

3mg/mL eye and ear drops

**Basic Succinct Statement**

**CODE: BSS RD 08 FEB 16; APPR 02 DEC 19**

**This material is only meant for Healthcare Professionals**

## COLIRCUSÍ\* GENTAMICIN

**Important note:** Before prescribing, consult full prescribing information.

**Presentation:** 10ml bottle – Each ml contains 3 mg gentamicin (sulphate) and 0.01 mg benzalkonium chloride as preservative.

**Indications:** Infections of the anterior pole of the eye caused by germs sensitive to gentamicin: corneal ulcers and corneal bacterial abscesses. Conjunctivitis. Keratitis. Staphylococci. Blepharitis. Dacryocystitis. Preoperative sterilization of the conjunctiva.

**Dosage and administration:** ♦ Instill 1 or 2 drops into the affected eye every 4 hours. ♦ In severe infections, dosage may be increased to 1 drop once every hour. ♦ The number of daily applications and length of treatment can be modified in accordance with physician's criteria.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients.

**Warnings and Precautions:** ♦ Sensitivity to topically administered aminoglycosides may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticarial, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. If hypersensitivity develops during use of this medicine, treatment should be discontinued. ♦ Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical gentamicin may also be sensitive to other topical and/or systemic aminoglycosides should be considered. ♦ Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic aminoglycoside therapy or when applied topically to open wounds or damaged skin. Although these effects have not been reported following topical ocular use of gentamicin, caution is advised when used concomitantly. ♦ Prolonged use of COLIRCUSÍ\* Gentamicin Eye and Ear Drops may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. ♦ COLIRCUSÍ\* Gentamicin Eye and Ear Drops contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of COLIRCUSÍ\* Gentamicin Eye and Ear Drops and wait at least 15 minutes before reinsertion. ♦ **Ability to drive and use machines:** Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

**Undesirable effects:** The following adverse reactions have been reported during clinical trials with COLIRCUSÍ\* Gentamicin Eye and Ear Drops and are classified according to the subsequent convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ) and very rare ( $< 1/10,000$ ). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

♦ **Common (1 to 10%):** photophobia, eye pruritus, ocular discomfort, irritation, ocular hyperaemia, hypersensitivity (ocular). ♦ **Uncommon (0.1 to 1%):** keratitis.

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