NOVARTIS

COLIRCUSÍ GENTADEXA (gentamicin 0.3%)

3mg/mL eye and ear solution

Basic Succinct Statement

CODE: BSS RD 21 JAN 18; APPR 21 FEB 19

This material is only meant for Healthcare Professionals

COLIRCUSÍ* GENTADEXA

Important note: Before prescribing, consult full prescribing information.

Presentation: Bottle. Each ml of solution contains 3 mg gentamicin (sulphate), 1 mg dexamethasone, 0.5mg tetryzoline hydrochloride and 0.04 mg Benzalkonium Chloride as a preservative.

Indications: ♦ **In Ophthalmology:** Topical treatment of infections of the anterior pole of the eye with inflammatory complications caused by germs sensitive to gentamicin. Infective and allergic conjunctivitis and blepharoconjunctivitis. Keratitis (superficial, deep, phlyctenular, sclerosing, acne rosacea). Scleritis and episcleritis. ♦**In ENT:** Ear infections such as external otitis and in all conditions where a corticosteroid-antibiotic therapy is indicated.

Dosage and administration: ♦**Use in ophthalmology:** Treatment is initiated with one or two drops instilled every 4 hours in severe infections, the frequency of instillation can be increased), which is reduced according to the clinical evolution. It is not recommended to use this product for more than 14 days, unless otherwise advised by physician. ♦**Use in ENT:** Normally three to four drops 3 times a day.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients. ♦**In Ophthalmic administration:** •Patients with narrow angle glaucoma. •Vaccinia, varicella, and other viral infection of cornea or conjunctiva. •Fungal diseases of ocular structures or untreated parasitic eye infections. •Mycobacterial ocular infections. ♦ **In ENT:** •Viral, fungal and untreated parasitic otic infections. •Known or suspected perforation of the eardrum.

Warnings and Precautions: ♦**General:** • Gentadexa should be used with caution in elderly and in patients with cardiovascular disease or in patients with sympathetic denervation (e.g. patients with insulin dependent diabetes, orthostatic hypotension, hypertension, hyperthyroidism) due to the risk for possible systemic effects. Caution is also recommended if the product is used in children. • Patients being treated with monoamine oxidase (MAO) inhibitors may experience a severe hypertensive crisis if administered a sympathomimetic drug such as tetryzoline. • 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. • Corticosteroids may reduce resistance to and aid in the establishment of bacterial, fungal, viral or parasitic infections and mask the clinical signs of infection. Because of the antibiotic ingredient, prolonged use of COLIRCUSÍ* GENTADEXA Eye and Ear Drops may result in overgrowth of non-susceptible organism. If superinfection occurs, appropriate therapy should be initiated. ♦**Ophthalmic administration:** • 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 with systemic aminoglycosides therapy**.** • Prolonged use of ophthalmic

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corticosteroids may result in ocular hypertension and/or glaucoma, which may lead to optic nerve damage, visual field defects, reduced visual acuity and posterior subcapsular cataract formation. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes). • In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently. This is especially important in pediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. COLIRCUSÍ* GENTADEXA Eye and Ear Drops is not approved for use in pediatric patients. • Cushing's syndrome and/or adrenal suppression associated with systemic absorption of ophthalmic dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). In these cases, treatment should not be discontinued abruptly, but progressively tapered. • Fungal infection should be suspected in patients with persistent corneal ulceration who have been or are receiving these drugs. Corticosteroids therapy should be discontinued if fungal infection occurs. • Topical ophthalmic corticosteroids may slow corneal wound healing. Topical NSAIDs are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. • In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. • Contact lens wear is discouraged during treatment of an ocular inflammation. COLIRCUSÍ* GENTADEXA Eye and Ear Drops contains benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses. Avoid use with 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* GENTADEXA Eye and Ear Drops and wait at least 15 minutes before reinsertion. ♦**Otic administration:** This product contains benzalkonium chloride, a preservative that may cause irritation or other skin reactions.

Adverse drug reactions: The following adverse drug reactions have been derived from post-marketing experience with Gentadexa via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, ADRs are presented in order of decreasing seriousness: • hypersensitivity • eye irritation • eye pain

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