

Gentamicin 0.3% eye drops

Newborn use only

2022

Alert	Gentamicin eye drops are not recommended for routine empirical treatment of bacterial conjunctivitis in neonates. Use under close supervision and in consultation with an ophthalmologist.
Indication	Treatment of bacterial eye infections including conjunctivitis caused by susceptible organisms.
Action	Inhibits protein synthesis by irreversibly binding to the 30S ribosomal subunit and causing cell membrane damage. Concentration-dependent bactericidal effect.
Drug type	Aminoglycoside
Trade name	Genoptic
Presentation	Eye drops 0.3% (3mg/mL gentamicin), 5 mL dropper- bottle.
Dose	Dose frequency depends upon severity of infection and response to treatment Mild conjunctivitis: 1 drop every 6 – 8 hours into the affected eye(s), continue 48 hours after healing. Severe conjunctivitis: initially 1 drop every 2 – 4 hours into the affected eye(s), then gradually decrease frequency as improvement occurs (e.g. to 1 drop every 6 hours). Consider intravenous (IV) gentamicin therapy in severe infection.
Dose adjustment	Therapeutic hypothermia – Not applicable ECMO – Not applicable Renal impairment – Not applicable Hepatic impairment – Not applicable
Maximum dose	
Total cumulative dose	
Route	Topical
Preparation	Not applicable
Administration	Instil 1 eye drop into the affected eye(s). After administering eye drop, gently press against the inner corner of eye to reduce systemic absorption. If other eye drop(s) are administered, wait for 5 minutes between drops.
Monitoring	
Contraindications	Hypersensitivity to gentamicin or any of the product ingredients
Precautions	Allergic reaction to an ocular aminoglycoside; cross-allergenicity may occur
Drug interactions	No data available.
Adverse reactions	Transient irritation, conjunctival hyperaemia, ocular hyperaemia, eye discharge, eye irritation, eye pain, eye oedema, hypersensitivity including eyelid irritation, eyelid oedema, eye swelling.
Compatibility	Not applicable
Incompatibility	Not applicable
Stability	
Storage	Store below 25°C. Discard container 4 weeks after opening
Excipients	Polyvinyl alcohol (Liquifilm), disodium edetate, sodium phosphate dibasic, sodium chloride, benzalkonium chloride as a preservative and purified water.
Special comments	
Evidence	<p>Background</p> <p>A 2012 epidemiological study identified gram negative bacteria to be the causative agent in 38% of infants presenting with conjunctivitis. ⁽³⁾ Gentamicin is a water-soluble aminoglycoside, active against a wide variety of gram-positive and gram-negative bacteria. Increasing resistance to gentamicin from gram positive organisms causing conjunctivitis resulted in a reduction in the use of gentamicin ophthalmic solution in recent years. ⁽⁴⁾</p> <p>Efficacy</p> <p>Limited evidence is available on topical antibiotics for bacterial conjunctivitis in neonates. No prospective trials specifically assessed topical gentamicin for bacterial conjunctivitis in neonates. Aminoglycoside treatment is therefore not recommended as the first-line antibiotic therapy for empirical treatment of neonatal bacterial conjunctivitis.</p> <p><u>Gentamicin vs placebo in bacterial conjunctivitis:</u></p> <p>A 2012 Cochrane review identified that clinical and microbiological remission was improved with topical antibiotic therapy. Meta-analyses on remission rates revealed that topical antibiotics were of benefit in</p>

	<p>improving 'early' (days two to five) clinical (risk ratio (RR) 1.36, 95% confidence interval (CI) 1.15 to 1.61) and microbiological (RR 1.55, 95% CI 1.37 to 1.76) remission rates.⁽⁵⁾</p> <p>Gentamicin vs alternative agents:</p> <p>A 2010 study compared the kinetics and speed of kill of <i>Streptococcus pneumoniae</i> and <i>Haemophilus Influenzae</i> following administration of topical moxifloxacin, tobramycin and gentamicin ophthalmic solutions. Moxifloxacin killed both organisms faster and more efficiently than both tobramycin and gentamicin, recommending it as a first line agent for treatment of bacterial conjunctivitis instead of an aminoglycoside agent.⁽⁴⁾ A further study has reviewed the clinical effect on 158 patients with culture positive bacterial conjunctivitis, following treatment with trimethoprim-polymyxin B, gentamicin or sulfacetamide ophthalmic for 10 days. This study identified similar clinical cure and bacteriological response rates for all three antibiotic agents comparatively.⁽⁶⁾ A Malaysian study compared the use of chloramphenicol and gentamicin ophthalmic solutions in the empirical treatment of patients with acute conjunctivitis (n=527). Among them, 218 had a confirmed diagnosis of ophthalmia neonatorum. Chloramphenicol was effective against the majority of the gram-positive isolates and some of the gram negative, however was ineffective against <i>Pseudomonas aeruginosa</i>. Comparatively, gentamicin was effective against most of the gram-negative isolates, particularly <i>Pseudomonas aeruginosa</i>, but not all of the gram positive isolates. Overall sensitivity of all bacterial isolates was however highest with chloramphenicol.⁽⁷⁾</p> <p>Safety:</p> <p>Adverse effect reporting has been uncommon with ophthalmic solutions for the treatment of neonatal bacterial conjunctivitis.⁽⁵⁾ A study by Cagle et al hypothesized that whilst aminoglycoside ophthalmic solutions are safe to use, the use of tobramycin ophthalmic solution is associated with less frequent adverse reactions than gentamicin ophthalmic solution, due to the preservatives used in gentamicin ointment (methyl and propyl paraben).⁽⁸⁾ The most frequent reported side effects with gentamicin 0.3% solution were ocular burning and irritation.⁽⁹⁾ A 2011 case report of 4 infants treated with topical gentamicin prophylaxis for ophthalmia neonatorum, reported self-limiting eyelid swelling and erythema which resolved within 72 hours of cessation. In 662 infants receiving ocular prophylaxis with gentamicin at this institution, the incidence of adverse ocular reaction was reported to be 0.6 per 100 infants.⁽¹⁰⁾</p>
<p>Practice points</p>	<p>ANMF consensus</p> <p>Proven bacterial conjunctivitis in the neonatal population should be treated with appropriate topical antibiotics to prevent progression of disease.</p> <p>Aminoglycoside treatment is not recommended as the first-line antibiotic therapy for empirical treatment of neonatal bacterial conjunctivitis due to limitations in available evidence.</p> <p>The most frequent reported side effects with gentamicin 0.3% solution have been recorded as ocular burning and irritation upon instillation, as well as self-limiting reactions of eyelid swelling and erythema which resolve within 72 hours of cessation.</p> <p>To treat severe bacterial keratitis, Gentamicin 0.9% (9mg/mL) fortified eye drops can be prepared in pharmacy aseptic suite</p>
<p>References</p>	<ol style="list-style-type: none"> 1. Genoptic (eye drops). MIMS online. Accessed on 12 July 2022. 2. Conjunctivitis. Therapeutic guidelines. (2022). Accessed on 12 July 2022. 3. Chen CJ, Starr CE. Epidemiology of gram-negative conjunctivitis in neonatal intensive care unit patients. <i>Am J Ophthalmol.</i> 2008;145(6):966-970. 4. Wagner, Rudolph S., et al. Kinetics of kill of bacterial conjunctivitis isolates with moxifloxacin, a fluoroquinolone, compared with the aminoglycosides tobramycin and gentamicin. <i>Clinical Ophthalmology (Auckland, NZ)</i> 4 (2010): 41. 5. Sheikh A, Hurwitz B, van Schayck CP, McLean S, Nurmatov U. Antibiotics versus placebo for acute bacterial conjunctivitis. <i>Cochrane Database Syst Rev.</i> 2012;(9). 6. Lohr JA, Austin RD, Grossman M, Hayden GF, Knowlton GM, Dudley SM. Comparison of three topical antimicrobials for acute bacterial conjunctivitis. <i>Pediatr Infect Dis J.</i> 1988;7(9):626-9. 7. Subramania A, Reddy SC. Topical chloramphenicol/gentamicin in the empirical treatment of acute conjunctivitis--is it rational? <i>Med J Malaysia.</i> 1996;51(4):491 8. Cagle G, Davis S, Rosenthal A, Smith J. Topical tobramycin and gentamicin sulphate in the treatment of ocular infections: multicentre study. <i>Curr Eye Res.</i> 1981;1(9). 9. Micromedex – Gentamicin (ophthalmic) – accessed on 6th July 2022. 10. Nathawad R, Mendez H, Ahmad A, Laungani S, Hoa BT, Garlick J, Hammerschlag MR. Severe ocular reactions after neonatal ocular prophylaxis with gentamicin ophthalmic ointment. <i>The Pediatric infectious disease journal.</i> 2011 Feb 1; 30(2):175-6.

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