

GENTACIN®

(Gentamicin Sulphate)

Guide for Healthcare Professionals

Information to Minimize the Risk of Ototoxicity and Vestibulotoxicity

- * Use of gentamicin-containing ear drops must be strictly restricted to patients with a confirmed intact tympanic membrane.
- * Prescribing should be restricted to cases with documented susceptibility of the microorganism to gentamicin based on antimicrobial susceptibility testing.
- * Medical staff and patients must be clearly instructed on safe administration and precautions.

**“This document is approved by The Executive Directorate of Pharmacovigilance,
at SFDA.”**

"Healthcare professionals should read this guide before prescribing or dispensing Gentacin, and refer to the SFDA-approved SPC and PIL for complete information."

Introduction

Important Safety Information for Healthcare Professionals

This educational material has been developed to support the safe and appropriate use of Gentacin® (Gentamicin Sulfate) Ear Drops and to reinforce awareness of the risks of ototoxicity and vestibulotoxicity associated with gentamicin-containing ear drops.

The objectives of this educational guide are to:

- Increase awareness of the risks of ototoxicity and vestibulotoxicity associated with gentamicin-containing ear drops.
- Reinforce appropriate patient selection and prescribing practices.
- Promote careful assessment of tympanic membrane integrity before initiating treatment.
- Encourage appropriate microbiological investigation where clinically indicated.
- Support the early recognition, management, and reporting of suspected adverse reactions.

Gentamicin is an aminoglycoside antibiotic indicated for the treatment of otitis externa. Although administered topically, gentamicin is associated with important safety concerns, including ototoxicity, vestibular damage, vestibular disorders, hearing loss, and irreversible partial or complete deafness in susceptible patients.

This guide has been prepared to provide healthcare professionals with important information on the safe use of gentamicin-containing ear drops and to support risk minimization activities aimed at reducing the occurrence of ototoxicity and vestibulotoxicity.

Healthcare professionals should be reminded that the use of gentamicin-containing ear drops should be restricted to patients with::

- A confirmed intact tympanic membrane: Alternative treatment options should be considered if there is any suspicion of tympanic membrane perforation or damage.
- Documented susceptibility of the causative microorganism to gentamicin based on culture and antimicrobial susceptibility testing, whenever appropriate and feasible.

Particular caution should be exercised in elderly patients, patients with renal impairment, patients with hepatic impairment, and patients receiving concomitant ototoxic or nephrotoxic medicines, as these factors may increase the risk of adverse effects

Important Safety Information

Healthcare professionals should be aware that gentamicin-containing ear drops may cause ototoxicity (hearing damage) and vestibulotoxicity (balance disorders). Reported reactions include hearing loss, vestibular disorders, vestibular damage, and irreversible partial or complete deafness.

Ototoxicity

Ototoxicity refers to damage to the auditory system that may impair hearing. Reported adverse reactions associated with gentamicin include:

Hearing loss

Partial deafness

Total deafness

Irreversible auditory injury

The risk of ototoxicity is dose-related and may be increased by certain patient factors and concomitant medical conditions.

Vestibulotoxicity

Vestibulotoxicity refers to damage to the vestibular system of the inner ear, which is responsible for balance and spatial orientation.

Reported vestibular adverse reactions associated with gentamicin include:

Vestibular damage

Vestibular disorders

Balance disturbances requiring clinical evaluation and monitoring

Healthcare professionals should consider vestibular toxicity when evaluating patients who develop new vestibular symptoms during treatment.

Patients at Increased Risk :

Particular caution should be exercised in:

- Elderly patients.
- Patients with renal impairment.
- Patients with hepatic impairment.
- Patients receiving concomitant nephrotoxic or ototoxic medications.
- Patients with a perforated tympanic membrane.

These factors may increase the risk of gentamicin-associated toxicity and should be considered before treatment initiation.

Patients Receiving Concomitant Ototoxic or Nephrotoxic Medicines

The risk of gentamicin-associated toxicity may increase when it is used concomitantly with medicines known to have ototoxic or nephrotoxic potential, including:

- Potent diuretics (e.g., furosemide, ethacrynic acid)
- Amphotericin
- Cisplatin
- Cyclosporin
- Certain cephalosporins

Whenever possible, concurrent use with potentially ototoxic or nephrotoxic medicines should be avoided unless clinically necessary. Appropriate benefit-risk assessment and monitoring are recommended.

➤ Key Recommendations for Healthcare Professionals Before Prescribing Gentamicin-Containing Ear Drops

- ✓ Confirm that the tympanic membrane is intact.
- ✓ Review patient-specific risk factors.
- ✓ Assess renal function.
- ✓ Assess hepatic function.
- ✓ Exercise particular caution in elderly patients.
- ✓ Review concomitant medications for ototoxic or nephrotoxic potential.
- ✓ Consider microbiological confirmation and susceptibility testing where appropriate.

➤ Prescriber Confirmation

Before prescribing gentamicin-containing ear drops, healthcare professionals should ensure that:

- ☐ No tympanic membrane perforation is present.
 - ☐ Treatment is clinically indicated.
 - ☐ Culture and susceptibility results have been reviewed where available.
 - ☐ Patient-specific risk factors have been assessed.
 - ☐ Concomitant medications have been reviewed.
 - ☐ The expected benefits outweigh the potential risks.
 - ☐ The patient has been counselled regarding the risks of ototoxicity and vestibulotoxicity.
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Reporting to the Saudi Food and Drug Authority (SFDA)

Healthcare professionals should report suspected adverse reactions to:

The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA)):

Call Center: 19999

E-mail: npc.drug@sfd.a.gov.sa

Website: <https://ade.sfda.gov.sa/>



Scan the QR Code to Report Side Effects

Riyadh Pharma Pharmacovigilance Department :

Medical and Cosmetic Products Company Ltd.

Abdul Malik Ibn Marwan Street

Al Mutamarat Riyadh, Saudi Arabia

Email: pv@riyadhpharma.com

Telephone: +966 11 461 4325 Ext. 305

Prompt reporting of suspected adverse reactions helps improve the understanding of the safety profile of gentamicin-containing products and contributes to the protection of public health.



References

1. Gentacin® (Gentamicin Sulphate 0.3% w/v) Summary of Product Characteristics (SmPC)
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Version 01, Date: February 2023.

2. Gentacin® (Gentamicin Sulphate 0.3% w/v) Package Information Leaflet (PIL).

Version 01, Date: February 2023.