

Important Safety Information

Apigen 0.3% Eye/Ear Drops Gentamicin

Patient Guide

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

Important Safety Information

Apigen 0.3% Eye/Ear Drops

Gentamicin

This patient guide contains important information you need to be aware of when receiving treatment with ear drops containing gentamicin. Please refer to the package leaflet for complete information.

Information about Gentamicin Ear Drops:

- Gentamicin ear drops is an aminoglycoside antibiotic used to kill the bacteria that cause ear infections.
- Always use gentamicin ear drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- If you forget to use your ear drops, apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal scheduled dose.

Important Side Effects:

Ear damage such as difficulty in keeping your balance or hearing loss

Important Safety Information When Using Gentamicin Ear Drops:

- **Inform your doctor before using the drops if you are taking any other medicines. In particular:**
 - Cephalosporins, amphotericin, cisplatin or cyclosporin which may increase the risk of kidney damage
 - Diuretic medicines such as ethacrynic acid or frusemide which may increase the risk of ear damage.
 - Curare-type muscle relaxants
- **Do not:**
 - Use more drops than prescribed.
 - Use the medicine more frequently than prescribed
 - Continue treatment for longer than recommended by your healthcare professional.
 - Share your ear drops with another person, even if they have similar symptoms.
 - Use the gentamicin ear drops if you are allergic to gentamicin, or any other aminoglycoside antibiotic.
 - Use the ear drops if you have a perforated or damaged eardrum (tympanic membrane).
Your doctor will examine your ear before prescribing these drops.

- Inform your doctor or pharmacist if you:
 - Have hearing problems or hearing loss.
 - Have balance problems or vestibular disorders.
 - Have kidney problems.
 - Have liver problems.
 - Have previously experienced side effects with gentamicin or other aminoglycoside antibiotics.
- Pay Attention to Changes in Hearing
 - While using Gentamicin Ear Drops, monitor yourself for any changes in hearing.
 - Tell your doctor immediately if you notice:
 - Hearing loss.
 - Reduced hearing.
 - Difficulty hearing conversations.
 - Any sudden changes in hearing.
 - These symptoms may indicate ototoxicity (hearing-related side effects).
- Pay Attention to Changes in Balance
 - Gentamicin may also rarely affect the balance system of the inner ear.
 - Tell your doctor immediately if you experience:
 - Balance disturbances.
 - Difficulty maintaining balance.
 - New balance-related symptoms.
 - These symptoms may indicate vestibulotoxicity (balance-related side effects).

Please read the Package Information Leaflet (PIL) carefully and follow the instructions provided by your healthcare professional.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Any suspected adverse reactions to Apigen should be reported to Saudi Food and Drug Authority via:



SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa

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

Also, you can report to Amman Pharmaceutical:



E-mail:

Ghadah.Alotaibi@ammanpharma.com

Mobile: +966507917875

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