



Please read this leaflet carefully before you start to use ABGENTA Eye/Ear Drops B.P. (Gentamicin Sulphate)

ABGENTA

Eye-Ear Drops

Composition
Gentamicin Sulphate BP
equivalent to Gentamicin base 0.3%w/v
Benzalkonium Chloride B.P.(as preservative).....0.01%w/v
Aqueous vehicle.....q.s

Pharmacological properties

ABGENTA contains an aminoglycoside antibiotic called Gentamicin sulphate. Gentamicin drops treat superficial eye/ear bacterial infections. It works by first, disrupting the outer bacterial membrane integrity. Secondly, Gentamicin in ABGENTA binds to the 30S ribosomal sub unit, prevents the initiation of protein synthesis thereby blocking the metabolism of the bacteria and this then kills the bacteria. Furthermore, Gentamicin exerts post antibiotic effect characterized by prolonged suppression of bacterial re-growth at sub-inhibitory concentrations. Gentamicin sulphate offers a wide spectrum of activity which includes susceptible strains of gram-positive organisms such as *Staphylococci* and *Streptococci* including *Streptomonas*. Also infections due to susceptible strains of gram-negative organisms such as *H. influenzae*, *E. coli*, *K. pneumoniae*, *Enterobacter aerogenes*, *H. aegyptius*, *Neisseria* species including *N. gonorrhoea* and *Pseudomonas aureginosa* are successfully managed with ABGENTA.

Indications

Eye: treatment of external ocular infections caused by eye wounds, bacterial infection, acute conjunctivitis, corneal ulcers, blepharitis, keratitis, and infections following surgery. Proved significantly effective in reducing postoperative ocular bacterial counts. Achieves cleaner, healthier postoperative eyes with less mucopurulent discharge and eyelid crusting.
Ear: treatment of bacterial infections of the ears, for example otitis externa or otitis media.

Dosage

One or two drops topically in the conjunctival sac(s) or ear(s) depending on affected area every four hours, in severe disease, drops may be used hourly, being tapered to discontinuation as the infection subsides.Or use as directed by a physician.

Contraindications:

ABGENTA is contraindicated in those patients who may be hypersensitive to any of its components. As with all eye preparations, containing Benzalkonium chloride, those using the drops should not wear soft contact lenses during treatment.

Precautions:

Prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections appear during treatment, the drug should be discontinued and appropriate measures should be taken.
A burning or stinging reaction that does not go away may mean you are allergic to this product. Stop using and call your prescriber or health care professional. Adverse drug reactions are not common with ophthalmic preparations.
In some circumstances this medicine may not be suitable for you.
- If you are pregnant or planning to become pregnant.
- If you are breast feeding a baby.

Drug interactions

ABGENTA applied topically is not likely to produce significant drug interactions, however monitoring should be done when used with the following medications because very serious, possibly fatal interactions may occur:

- Other drugs that may also affect hearing and kidneys, such as cefadroxil, tenoflovir, clodrabine

Side effects

Occasional transient irritation may occur with ABGENTA. Also, burning, stinging or irritation, sensations may be experienced. Other serious side-effects are rare from the use of eye products;they include difficulty in hearing, dizziness, increased thirst, loss of balance, muscle weakness, nausea, pain or difficulty passing urine.

Presentation

Clear, faintly yellow solution in sterile plastic dropper bottles of 10ml and 5ml enclosed in protective carton with leaflet.

Shelf life

The manufacturing and expiry dates are indicated on the packaging.

Storage
Store below 30°C but do not freeze; protect from light.
Discard after the expiration date or one month after opening the bottle.

KEEP THE DROP OUT OF CHILDREN'S REACH.

Direction for use

Tighten the cap on the nozzle.
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.
Replace the cap after every use.

Warning

1. If irritation persists or increases, discontinue the use and consult a physician.
2. Do not touch the vial tip or other dispensing tip to any surface since this may contaminate the solution.
3. Use the solution within one month after opening the vial.
4. Keep the vial in the carton box after every use.

Wash your hands well before use.

For the Eye Drops:

1. Remove the outer cap.
2. Tilt the head back and pull the lower lid of the eye down to form a pocket.
3. Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the eye, and try not to touch the eye.
4. Apply enough pressure to the container to release one to two drops.
5. Close the eye and keep it closed for one to two minutes.
6. If you think you have missed the eye, then insert another drop.
7. Repeat in the other eye if you have been instructed to use this preparation in both eyes.
8. Replace the outer cap on the container, try not to touch the applicator tip with the fingers as you do so.
9. Wash your hands.

For the Ear Drops:

1. Clean the ear with warm water and dry thoroughly.
2. Remove the outer cap.
3. Lie down or tilt the head so that the affected ear is facing upwards.
4. Gently pull the ear lobe to straighten the ear canal.
- 5- Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the ear, and try not to touch the inside of the ear.
6. Apply enough pressure to the container to release three to four drops of ABGENTA.
7. Keep the ear facing up for a few minutes to allow the solution to come into contact with the affected area.
8. Repeat in the other ear if you have been instructed to use ABGENTA drops in both ears.
9. Replace the outer cap on the container.
10. Wash your hands.

For further information, please consult your pharmacist or physician

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