庆大霉素说明书8x21cm 正反面印

GMYCIN - 80

Gentamycin Injection BP 80mg/2ml

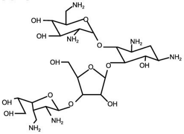
40 mg/ml (80 mg/2 ml) solution for Injection (I.M/I.V)

COMPOSITION:

Each ml contains:

Gentamicin Sulphate BP equivalent to Gentamicin base (40,000 IU)	40 mg
Methyl Paraben BP	1.8 mg
Propyl Paraben BP	0.2mg
Water for injection BP	q.s

CHEMICAL STRUCTURE:



PHARMACOLOGY & MECHANISM OF ACTION:

Gentamicin is an aminoglycoside antibiotic that interferes with bacterial protein synthesis by binding primarily to the 30S sub-unit of bacterial ribosomes in susceptible organisms. Cell death results.

Active against a wide range of aerobic Gram-negative and some Gram-positive organisms including E.coli, Enterobacter, Klebsiella, Proteus, Providentia Pseudomonas, Campylobacter, Citrobacter, Serratiia, Staph.aureus, Staph.epidermidis and listeria monocytogenes.

PHARMACOKINETICS:

Gentamicin is rapidly absorbed after IM injection and peak serum levels are usually achieved within 30 to 90 minutes and are measurable for 6-8 hours. Following parenteral administration, gentamicin can be detected in tissues and body fluids. Penetration occurs into the bile, pleural and pericardial fluids and the perilymph of the inner ear but little, if any, penetrates the blood/brain barrier or diffuses into the eye. Gentamicin crosses the placenta but only small amounts have been reported in breast milk. Binding of gentamicin to plasma proteins is usually low.

Gentamicin does not appear to be metabolised and is excreted virtually unchanged in the urine almost entirely by renal glomerular filtration, hence the half-life of the medicine is prolonged in the presence ofrenal failure.

The serum half-life of gentamicin is approximately 2-3 hours in adults with normal renal function. It is prolonged in patients with impaired renal function and in premature or new born infants. At steady-state at least 70% of dose may be recovered in the urine within 24 hours. However, gentamicin does accumulate in body tissues to some extent, mainly in the kidney and release from these sites is slow and it may be detected in the urine for up to 20 days or more after administration ceases.

INDICATIONS AND USES:

Serious gentamicin sensitive infections. Valuable in critically ill patients with impaired host defence. Pseudomonas or Proteus infections; burns, urinary tract infections, lung abscesses, Osteomyelitis, middle ear infection, septicaemia, Meningitis caused by gram negative bacilli. Bacteraemia, peritonitis in skin and soft tissue infections, post-operative infection.

DOSAGE AND ADMINISTRATION:

Adults: 3-5mg/kg body-weight I.M or I.V. daily in divided doses 8 hourly for 7-10 days.

ADVERSE REACTIONS:

Ototoxicity (incidence is related to dese and duration of therapy), nephrotoxicity, hypersensitivity reactions, skin itching, headache, neuromuscular junction blockade, anorexia, nausea, vomiting, superinfection, photosensitivity, drowsiness, weakness, thrombocytopenia, agranulocytosis.

OVERDOSAGE:

As gentamicin is almost entirely eliminated by the kidneys, fluid loading may hasten its elimination and to a lesser extent peritoneal dialysis will also aid in the removal of gentamicin calcium salts given intravenously have been used to counter neuro-muscular blockade.

CONTRAINDICATIONS:

Gentamicin is contraindicated in patients with a history of hypersensitivity to gentamicin or who have experienced previous toxic reactions (ototoxicity, nephrotoxicity) resulting from aminoglycoside therapy.

Nephrotoxicity and ototoxicity: As for other aminoglycosides, patients being treated with gentamicin should be under close clinical observation.

ALLERGIC REACTIONS:

May occur after administration of gentamicin.

Aminoglycosides should be used cautiously in patients with neuromuscular disorders such as myasthenia gravis or parkinsonism.

PRECAUTIONS:

Gentamicin dose is to be given on body weight basis and according to renal function.

DRUG INTERACTIONS:

Amphotercin B, Cisplatin, Cephalosporin, : Increasednephrotoxicity.
Vancomycin, Methoxyflurane, Frusemide,
Bumetanide
Anaesthetics, Neuromuscular blocking : Risk of neuromuscular blockade
agents (Tubocurarine) and respiratory paralysis.
Penicillin, Cephalosporins, Carbenicillin : Exerts antibiotic synergism,
Tocarcillin especially useful in pseudomonas Infections

Loop diuretics	: Concurrent use of these agents may increase the risk of respiratory paralysis and renal dysfunction
Lab tests	: Aminoglycoside serum levels: guard against in vitro inactivation by Beta lactum antibiotics in Patients in combination therapy.

USE IN PREGNANCY:

Category D. Gentamicin crosses the placenta. Safety for use in pregnancy in regard to potential for ototoxicity or nephrotoxicity has not been established. All aminoglycosides should be considered potentially nephrotoxic and ototoxic to the foetus. Therapeutic blood levels in the mother do not necessarily equate to safety for the foetus. It is therefore advisable not to use gentamicin during pregnancy unless deemed essential by the physician and the expected benefits of therapy outweigh any potential risk.

USE IN LACTATION:

Small amounts of gentamicin have been detected in breast milk. Because of the potential risk to the newborn, it is recommended that breast feeding be discontinued during therapy unless the expected benefits outweigh any potential risk.

CARCINOGENICITY AND MUTAGENICITY:

No data is available on this at present.

STORAGE:

Store in a dry place below 25ºC.
Protect from direct sunlight.
Keep away from children's reach.

WARNING:

Contains sodium metabisulfite. Sulfite that may cause allergic type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible persons.

SHELF-LIFE:

3 years from the date of manufacturing.

Manufactured by:
Reyoung Pharmaceutical Co., Ltd.
No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R.China

ABACUS

Manufactured for:
Abacus Pharma(A) Limited
East Africa