Gentin®

Gentamicin

Description: Gentamicin (**Gentin®**) is a bactericidal antibiotic of Aminoglycoside class and is used against a wide range of infections. It is available in the form of injection and cream.

Mode of action: Gentamicin (**Gentin®**) acts by irreversible inhibition of protein synthesis by binding to the 30s subunit of bacterial ribosome. As a result the bacteria grow without any functional protein and ultimately are killed.

Pharmacokinetics: Gentamicin (**Gentin®**) and other aminoglycosides are poorly absorbed from the gastrointestinal tract but are rapidly absorbed after intramuscular injection. Average peak plasma concentrations of about 4 mcg/ml have been attained in patients with normal renal function, 30 to 60 minutes after an intramuscular dose equivalent to gentamicin 1 mg/kg, which is similar to concentrations achieved after intravenous infusion. Systemic absorption of gentamicin and other aminoglycosides has been reported after topical use on denuded skin and burns and following instillation into, and irrigation of, wounds, body-cavities (except the urinary bladder), and joints.The plasma elimination half-life for gentamicin has been reported to be 2 to 3 hours though it may be considerably longer in neonates and patients with renal impairment. Gentamicin and other aminoglycosides do not appear to be metabolised and are excreted virtually unchanged in the urine by glomerular filtration.

Composition:
Gentin® 80 mg Injection: Each ampoule (2 ml) contains Gentamicin Sulfate BP 135.59 mg equivalent to Gentamicin 80 mg.
Gentin® 20 mg Injection: Each ampoule (2 ml) contains Gentamicin Sulfate BP 33.828 mg equivalent to Gentamicin 20 mg.
Gentin® Cream: Each 100 gm cream contains Gentamicin Sulfate BP 508.5 mg equivalent to Gentamicin 300 mg.

Indications: Injection: Sepsis with gram-negative bacteria, pelvic inflammatory disease, urinary tract infections, pre- and post-surgical prophylaxis, peritonitis, bacterial meningitis, infected burn, septic abortion, cellulitis, bacterial endocarditis, etc.
Cream: Primary and secondary bacterial skin infections, infected burn, bedsore, skin infections resistant to other antibiotics.

Dosage & administration: Gentamicin is normally given by the intramuscular route, but can be given intravenously when intramuscular administration is not feasible, e.g. in shocked or severely burned patients. When given intravenously, the prescribed dose should be administered slowly over 2 to 3 minutes directly into a vein or into the rubber tubing of a giving set. The same dosage schedule is recommended for intramuscular and intravenous dosing. Dosage is related to the severity of infection, the age of the patient and the patient's renal function. Dosage is adjusted for patients with renal impairment to minimize the risk of toxicity. The first dose should be as normal and after this, doses should be given less frequently, the interval being determined by results of renal function test.
Injection:

Adult Dosage			
Type of infection	**Dosage**	**Time interval between doses**	**Duration of therapy**
Systemic and urinary tract infections	3 mg/kg/ day upto 80 mg	8 hours	7 to 10 days
Life threatening infections	5 mg/kg/day initially then 3 mg/kg/day as soon as improvement is indicated	6 to 8 hours	7 to 10 days (Longer therapy may be required. If so, auditory renal and vestibular functions should be monitored)

Pediatric Dosage			
Type of infection	**Age**	**Dose and route**	**Frequency**
Systemic	Upto 7 days	5 mg/kg/day IM	12 hours
	1 week to 1 year	6 mg/kg/day IM	12 hours
	1 year to 12 years	4.5 mg/kg/day IM	8 hours
Urinary tract infections		3 mg/kg/day IM	8-12 hours
Life threatening infections	Upto 7 days	5 mg/kg/day	12 hours
	1 week to 1 year	7.5 mg/kg/day	8 hours
	1 year to 12 years	6 mg/kg/day	8 hours

Cream: The affected area should be properly cleaned and the cream to be used 2-3 times daily until total recovery.

Contraindications: Gentamicin is contraindicated in patients with a known history of hypersensitivity to it, and probably in those hypersensitive to other aminoglycosides. It should be avoided in patients with myasthenia gravis.

Side effects: Vestibular and auditory damage, nephrotoxicity may occur rarely in case of use of gentamicin. Hypomagnesaemia on prolonged therapy, antibiotic-associated colitis, stomatitis, nausea, vomiting, rash, blood disorders may also be reported.

Use in pregnancy & lactation: Short courses of gentamicin may be used in pregnancy if no safer treatment is available. It should be used with caution in lactation.

Precautions: The drug should be used with caution in renal impairment and concomitant administration of nephrotoxic drugs.

Drug interactions: Use of other nephrotoxic drugs, including other aminoglycosides, vancomycin, some cephalosporins, ciclosporin, cisplatin, and fludarabine, or of potentially ototoxic drugs such as etacrynic acid and perhaps furosemide, may increase the risk of aminoglycoside toxicity.

Overdosage: In the event of overdosage or toxic reactions, haemodialysis may aid in the removal of gentamicin from the blood, especially if renal function is, or becomes, compromised. The rate of removal of gentamicin is considerably lower by peritoneal dialysis than it is by haemodialysis. In the newborn infant, exchange transfusions may also be considered.

Storage: Store in a cool and dry place, protected from light.

Packaging
Gentin® 80 mg Injection: Each carton contains 5X5 ampoules in blister pack.
Gentin® 20 mg Injection: Each carton contains 5X5 ampoules in blister pack.
Gentin® Cream: Each carton contains a tube having 10 gm cream.

389-03

Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.