Cidomycin® Injectable Preparations
Cidomycin® Intrathecal Injection

Gentamicin Injection BP
Gentamicin Sulphate BP

Indications

Cidomycin is a bactericidal antibiotic active against an extremely broad spectrum of Gram-positive and Gram-negative pathogens including *Escherichia coli, Klebsiella, Proteus, Pseudomonas aeruginosa* and antibiotic-resistant strains of *Staph aureus*. Cidomycin is often active against strains resistant to streptomycin and kanamycin as well as other unrelated antibiotics.

Cidomycin injectable and Cidomycin paediatric injectable are indicated in urinary-tract infections, chest infections, bacteraemia, septicaemia, infections following burns, infected traumatic or surgical wounds and other systemic infections due to sensitive organisms.

Cidomycin Intrathecal Injectable is indicated as a supplement to systemic therapy in bacterial meningitis, ventriculitis and other bacterial infections of the central nervous system.

Routes of Administration

Cidomycin is usually given intramuscularly, but may be given intravenously if necessary, e.g. in patients with shock, in severe burns or reduced muscle mass. The same dosages are recommended for intramuscular and intravenous use. When given intravenously a bolus injection should be made into the tubing of the giving set or directly into a vein over a period of two or three minutes. Cidomycin may also be administered by infusion, in sterile normal saline or in a sterile solution of dextrose 5% in water, provided this is completed within 20 minutes and in no greater volume of fluid than 100ml. Cidomycin Injectable should not be mixed with any drug prior to administration.

Dosage and administration

Gentamicin injection:

Adults:

1. *Serious infections:* 5mg/kg daily in equally divided doses at six-or eight-hourly intervals, in the absence of impaired renal function. The total daily dose may be subsequently increased or decreased as clinically indicated.
2. *Other systemic infections:* 80mg eight-hourly for 7-10 days is usually an effective dose. If body weight is less than 60kg, 60mg eight-hourly should be used.
3. *Urinary tract infections:* As for systemic infections or if renal function is not impaired, 160mg once daily.

Children:

Up to 2 weeks of age: 3mg/kg twelve-hourly.
2 weeks to 12 years: 2mg/kg eight-hourly.

Assay of peak serum levels gives confirmation of adequacy of dosage and also serves to detect levels above 10μg/ml at which the possibility of ototoxicity should be considered.
Gentamicin is excreted by simple glomerular filtration and therefore is given in reduced dosage in cases of renal impairment.
The following table may be used when treating adults.

Blood urea (mg/100ml)	(mmol/l)	Creatinine clearance (GFR) (ml/min)	Dose and frequency of administration
<40	6-7	>70	80mg*8 hourly
40-100	6-17	30-70	80mg*12-hourly
100-200	17-34	10-30	80mg*daily
>200	>34	5-10	80mg*every 48 hours
Twice-weekly intermittent haemodialysis		<5	80mg*after dialysis

*60mg if body weight <60kg.

Frequency of dosage in hours may also be approximated as serum creatinine (mg %) x eight or in SI units: as serum creatinine (μ mol/l) divided by 11. If these dosage guides are used peak serum levels must be measured. Peak levels of gentamicin occur approximately one hour after intramuscular injection and 15 minutes after bolus intravenous injection. Trough levels are measured just prior to the next injection.

Gentamicin intrathecal injection: Bacterial meningitis and ventriculitis: the starting dose of gentamicin intrathecal injection for both children and adults is 1mg daily, intrathecally or intraventricularly, together with 1mg/kg every eight hours intramuscularly. The MIC of the infecting organism in the CSF should be assessed and, if necessary, the intrathecal/intraventricular dose increased to 5mg daily whilst keeping the intramuscular dose at 1mg/kg eight-hourly. Treatment should be continued for at least seven days but longer if necessary. Periodic serum and CSF gentamicin assays should be carried out to ensure that adequate antibiotic levels are maintained and that serum and CSF levels do not exceed 10μg/ml.

Contra-indications, Warnings etc.

Cidomycin should not be used during pregnancy, except in life-threatening situations. Neither should it be used if there is a history of sensitivity to the antibiotic. Vestibular damage (hearing loss has seldom been manifest) has been recorded following the use of gentamicin usually in the presence of impaired renal function following higher dosage or more prolonged administration than that recommended. In some patients with impaired renal function there has been a transient rise in blood-urea-nitrogen which has usually reverted to normal during, or following cessation of therapy. Frequency of dosage should be reduced in impaired renal function (see above).

There is evidence that any potential nephrotoxicity of cephalosporins, and in particular cephaloridine, may be increased in the presence of gentamicin. If this combination is used monitoring of kidney function is advised. Concurrent administration of Cidomycin and potentially ototoxic or nephrotoxic substances should be avoided. Neuromuscular blockade and respiratory paralysis have been reported from administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia.

Pharmaceutical Precautions

Cidomycin is heat stable and does not require refrigeration.

Physical and/or chemical incompatibilty occurs between Cidomycin Injectable and the following substances: penicillins, cephalosporins, erythromycin, lipiphysan, heparins, sodium bicarbonate.

Cidomycin should not be mixed in the same syringe with any of these substances. It may, however, be administered concurrently with any of them but at separate sites.

Cidomycin and incompatible substances may be injected by bolus consecutively into the drip tubing of a suitable intravenous infusion with adequate interim flushing.

If an incompatible antibiotic is being given by continuous infusion, Cidomycin Injectable may be given by bolus into the drip tubing with adequate flushing.

Product Licence Numbers

2ml vials or ampoules 80mg	PL0109/5065	PA6/3/4 PA6/3/7
Paediatric 2ml vials 20mg	PL0109/5066	PA6/3/5
Intrathecal 5mg	PL0109/0057	PA6/3/1

Packs and Presentations

- *Cidomycin injectable* in 2ml vials or 2ml ampoules each containing the equivalent of 80mg gentamicin base (as sulphate). Packs of 25 x 2ml vials (dust cap coded red) or 25 x 2ml ampoules
- *Cidomycin injectable Paediatric* in 2ml vials each containing the equivalent of 20mg gentamicin base (as sulphate). Packs of 5 x 2ml vials (dust cap coded blue).
- *Cidomycin intrathecal* injectable in 1ml ampoules each containing 5mg gentamicin base (as sulphate). Packs of 5 x 1ml ampoules.

Roussel Laboratories Ltd.,
Uxbridge UB9 5HP England

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CDE 02613