Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cidomycin Intrathecal Injectable 5 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule (1ml) contains Gentamicin Sulphate equivalent to 5mg (5000 international units) of gentamicin.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection
Sterile, clear, colourless aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Gentamicin intrathecal injectable is indicated for the treatment of meningitis and ventriculitis due to bacteria sensitive to this anti-infective.

4.2 Posology and method of adminstration

The usual daily dose by the intraventricular or intrathecal route is 1mg gentamicin base. The dose can be controlled by the physician on the basis of CSF levels of drug. Duration of treatment is dependent on microbiological clearing of the CSF. If the MIC of the infecting organisms so requires, an intrathecal/ventricular dose up to 5mg daily can be given in addition to the above treatment. Gentamicin should be given intramuscularly according to the following suggested schedules :

Adults : 2 to 4 mg/kg every 24 hours in divided doses at 8 hour intervals.

Children - (infants over 2 weeks up to children aged 12 years): 6.0 mg/kg in three equal divided doses.

Infants up to 2 weeks: 6.0 mg/kg/day in two equal divided doses.

Patients with renal impairment :

creatinine clearance ml/min	dose mg	frequency of administration
> 70	80	8 hourly
30 – 70	80	12 hourly
10 – 30	80	24 hourly
5 – 10	80	48 hourly
5 with haemodialysis	80	after dialysis

Frequent assays of gentamicin levels in serum and CSF should be carried out to avoid levels > 10µg/ml.

4.3 Contraindications

1. Use in patients hypersensitive to gentamicin or other related aminoglycosides.

2. Concurrent use with other potentially nephrotoxic or ototoxic agents.

4.4 Special warnings and precautions for use

1. In addition to nephrotoxicity and ototoxicity, anaemia, purpura, convulsions, increased liver function tests and anaphylaxis may occur.

2. In patients with renal dysfunction the frequency and quantity of dosing may require reduction to avoid toxicity from serum concentrations, in excess of 10µg/ml.

3. In view of the concentration of gentamicin per ml in this formulation it is essential to ensure that the correct volume and dosage is not inadvertently exceeded.

4. Renal and auditory function should be carefully and regularly monitored during gentamicin therapy.

4.5 Interaction with other medicinal products and other forms of interaction

1. Concurrent use with cephalosporins or loop diuretics may potentiate nephrotoxicity.

2. Gentamicin, as do other aminoglycosides may induce neuromuscular blockage and respiratory paralysis. It should therefore only be used with great caution in patients receiving curare-type muscle relaxants.

3. Gentamicin and carbenicillin exert a synergistic effect on combination.

4.6 Pregnancy and lactation

Gentamicin should only be used during pregnancy and lactation if considered essential by the physician. The drug crosses the placenta but does not reach breast milk in measurable levels. There is a possibility of damage to the auditory nerve of the foetus.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

See “special warnings & precautions for use”.

4.9 Overdose

Haemodialysis and peritoneal dialysis will aid the removal from blood but the former is probably more efficient. Calcium salts given intravenously have been used to counter the neuromuscular blockade caused by gentamicin.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A broad spectrum bactericidal antibiotic which by the usual systemic route does not cross the blood brain barrier to any significant degree.

5.2 Pharmacokinetic properties

Intrathecally administered the drug is eliminated into systemic circulation to kidney for excretion by glomerular filtration with a $t_{1/2}$ of about 4 hours.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections

6.2 Incompatibilities

In general, Gentamicin Injection should not be mixed with other drugs prior to administration. In particular the following are incompatible in mixed solution with gentamicin injection: penicillins, cephalosporins, erythromycin, heparins, sodium bicarbonate*. Dilution in the body will obviate the danger of physical and chemical incompatibility and enable gentamicin to be given concurrently with the drugs listed above either as a bolus injection into the drip tubing, with adequate flushing, or at separate sites. In the case of carbenicillin, administration should only be at a separate site.

* Carbon dioxide may be liberated on addition of the two solutions. Normally this will dissolve in the solution but under some circumstances small bubbles may form.

6.3 Shelf Life

Unopened: 36 months.
Opened: Once opened, the contents of the ampoule should be used immediately. Any unused contents should be disposed of appropriately.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Cidomycin Intrathecal Injectable is supplied in 1 ml neutral clear colourless type I glass ampoules in packs of 5.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 6/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 June 1976

Date of last renewal: 10 June 2001

10 DATE OF REVISION OF THE TEXT

December 2001