

**Gentamicin injection**  
**80mg/2ml**

**Submitted by**

**Anhui Chengshi Pharmaceutical Co., Ltd.**

**No. 5068, Huaishang Road, Bengbu, Anhui Province, P.R. Of China**

**Confidential**

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## **MODULE 1:**

# **ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION**

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### **1.3 Product Information**

#### **1.3.1 Summary of Product Characteristics (SmPC)**

##### **1. Name of the medicinal product**

Gentamicin injection 80mg/2ml

##### **2. Qualitative and quantitative composition**

Each 2ml contains: Equivalent to 80mg of gentamicin.

##### **3. Pharmaceutical form**

Injection

A clear, colourless to slightly yellow or slightly yellow green liquid

##### **4. Clinical particulars**

###### **4.1 Therapeutic indications**

Indications : gentamicin is indicated in bacteraemia, urinary tract infections, chest infections, severe neonatal infections and other serious systemic infections due to susceptible organisms, in adults and children including neonates.

Consideration should be given to official local guidance on the appropriate use of antibacterial agents.

###### **4.2 Posology and method of administration**

###### **Adults:**

Systemic infections: if renal function is not impaired, 3-5 mg/kg/day in divided doses according to severity of infection, adjusting according to clinical response and body weight.

Serious infections: if renal function is not impaired, 5mg/kg daily in divided doses at six or eight hourly intervals. The total daily dose may be subsequently increased or decreased as clinically indicated.

Urinary tract infections: as 'systemic infections'. Or, if renal function is not impaired, 160mg once daily may be used.

###### **Paediatric Patients:**

The daily dose recommended in children (aged 1 year and above) and adolescents with normal renal function, is 3-6 mg/kg body weight per day as 1 single dose (preferred) or up to 2 single doses.

The daily dose in infants after the first month of life is 4.5-7.5 mg/kg body weight per day as 1 single dose (preferred) or up to 2 single doses.

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The daily dose in neonates is 4-7 mg/kg body weight per day. Due to the longer half-life, neonates are given the required daily dose in 1 single dose.

**Elderly:**

There is some evidence that elderly patients may be more susceptible to aminoglycoside toxicity whether secondary to previous eighth nerve impairment or borderline renal dysfunction.

Accordingly, therapy should be closely monitored by frequent determination of gentamicin serum levels, assessment of renal function and signs of toxicity.

**Renal impairment:**

Gentamicin is excreted by simple glomerular filtration. In impaired renal function, the recommended daily dose has to be decreased and adjusted to the renal function.

Nomograms are available for the calculation of the dose, which depends on the patient's age, weight, and renal function

The following table may be useful when treating adults.

<b>Blood Urea</b>		<b>Creatine clearance</b>	<b>Dose and frequency of administration</b>
(mg/100ml)	(mmol/l)	(GFR) (ml/min)	
<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 creatine (mg%) x eight or in SI units, as serum creatine ( $\mu\text{mol/l}$ ) 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 injectable and intravenous injectable. Trough levels are measured just prior to the next injectable. Assay of peak serum levels gives confirmation of adequacy of dosage and also serves to detect levels above 10mg/l, at which the possibility of ototoxicity should be considered. One hour concentrations of gentamicin should not exceed 10mg/l (but should reach 4mg/l), while the pre-dose trough concentration should be less than 2mg/l*

The recommended dose and precautions for intramuscular and intravenous administration are identical. Gentamicin when given intravenously should be injected directly into a vein or into the drip set tubing over no less than three minutes. If

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administered by infusion, this should be over no longer than 20 minutes and in no greater volume of fluid than 100ml.

Monitoring advice:

Serum concentration monitoring of gentamicin is recommended, especially in elderly, in newborns and in patients with impaired renal function. Samples are taken at the end of a dosing interval (trough level). Trough levels should not exceed 2 µg/ml administering gentamicin twice daily and 1 µg/ml for a once daily dose.

#### **4.3 Contraindications**

Hypersensitivity to gentamicin or any of the excipients; myasthenia gravis.

#### **4.4 Special warnings and precautions for use**

In patients with advanced renal impairment or with pre-existing inner ear deafness, gentamicin should be used only if its use is considered essential by the physician. The frequency or dose of administration should be reduced in patients with impaired renal function.

##### Renal impairment

Renal impairment such as restriction of glomerular filtration is observed in approximately 10% of patients treated with gentamicin and is usually reversible. The most important risk factors are high total dose, long duration of therapy, raised serum level (high trough level); in addition, other potential risk factors are age, hypovolaemia and shock.

Clinical signs of renal damage are: proteinuria, cylindruria, haematuria, oliguria, raised creatinine and urea concentrations in serum. In isolated cases, acute renal failure may occur.

##### Neuromuscular disorders

Since gentamicin has neuromuscular blocking properties, particular caution should be exercised in patients with pre-existing neuromuscular diseases (e.g. Parkinson's disease). Particularly careful monitoring is mandatory.

Neuromuscular blockade and respiratory paralysis have been reported from administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia. These patients should also be monitored very carefully.

##### Effect on vestibulocochlear nerve

Damage to the vestibulocochlear nerve (eighth cranial nerve), whereby both balance and hearing may be affected, is possible. Vestibular damage is the most common ototoxic reaction. Hearing loss is manifested initially by diminution of high-tone acuity and is usually irreversible. Important risk factors are pre-existing renal impairment or a history of damage to the eighth cranial nerve; in addition, the risk increases in proportion to the level of the total and daily dose or by association with

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potentially ototoxic substances. Symptoms of ototoxic effects are: dizziness, ringing/roaring in the ears (tinnitus), vertigo and less common hearing loss.

With gentamicin the vestibular mechanism may be affected if trough levels of 2 µg/ml are exceeded. This is usually reversible if observed promptly and the dose adjusted.

Antibiotic-associated diarrhoea, pseudomembranous colitis Antibiotic-associated diarrhoea and pseudomembranous colitis have been reported with the use of gentamicin. These diagnoses should be considered in any patient who develops diarrhoea during or shortly after treatment. Gentamicin should be discontinued if severe and/or bloody diarrhoea occurs during treatment and appropriate therapy instituted. Drugs that inhibit peristalsis must not be given.

#### Pregnancy and lactation

Gentamicin should be used in pregnancy and during lactation only after careful benefit risk assessment.

#### Once daily dosing of gentamicin in elderly patients:

There is limited experience with once daily dosing of gentamicin in elderly patients. Once daily dosing of gentamicin may not be suitable and therefore, close monitoring is warranted in these patients.

#### Excipients

This medicine contains 0,78 mg of sodium per ampoule (less than 23 mg per ampoule), i.e. it is essentially sodium free.

Sodium metabisulphite, one of the excipients of this medicinal product, may rarely cause severe hypersensitivity reactions and bronchospasm.

#### Cross-allergenicity/-resistance

Cross resistance and hypersensitivity to aminoglycosides may occur.

#### Monitoring

To avoid adverse events, continuous monitoring (before, during and after treatment) of renal function (serum creatinin, creatinin clearance), control of function of vestibule and cochlea as well as hepatic and laboratory parameters is recommended.

In order to reduce the risk of nephrotoxicity and ototoxicity, the following instructions should be considered:

– Regular assessment of auditory, vestibular and renal function is particularly necessary in patients with additional risk factors. Impaired hepatic function or auditory function, bacteraemia and fever have been reported to increase the risk of ototoxicity. Volume depletion or hypotension and liver disease have been reported as additional risk factors for nephrotoxicity.

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- Monitoring of renal function before, during and after treatment.
- Dosage strictly according to creatinine clearance (or serum creatinine concentration). In patients with impaired renal function, the dosage must be adjusted according to renal performance.
- In patients with impaired renal function additionally receiving gentamicin locally (inhalation, intratracheal, instillation), the amount of gentamicin absorbed after local administration must also be taken into account for dose adjustment of systemic treatment.
- Monitoring of serum gentamicin concentrations during therapy in order to avoid that peak levels exceed 10 µg/ml (toxic threshold for the cochleo-vestibular system) with conventional multiple daily dosing or trough levels exceed 2 µg/ml when administering gentamicin twice daily and 1 mg/l for a once daily dosing.
- In patients with pre-existing inner ear damage (hearing impairment or balance function impairment), or where treatment is long-term, additional monitoring of the balance function and hearing is required.
- Prolonged treatment should be avoided. If possible, the duration of therapy should be limited to 7 – 10 days.
- Avoid therapy with aminoglycosides immediately subsequent to previous aminoglycoside treatment; if possible, there should be an interval of 7 – 14 days between treatments.
- If possible, avoid concurrent administration of other potentially ototoxic and nephrotoxic substances. If this is unavoidable, particular careful monitoring of renal function is indicated.
- Ensure adequate hydration and urine production.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

##### **Muscle relaxants and ether**

The neuromuscular blocking activity of aminoglycosides is enhanced by ether and muscle relaxants.

If gentamicin is administered during or immediately after surgery, the neuromuscular blockade may be enhanced and prolonged if non-depolarising muscle relaxants are used. These interactions may cause neuromuscular blockage and respiratory paralysis. Because of the increased risk, such patients should be monitored with particular care.

Injection with calcium chloride may reverse the neuromuscular blockade due to aminoglycosides but should be undertaken with caution.

##### **Methoxyflurane anaesthesia**

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Aminoglycosides may increase the kidney damaging effect of methoxyflurane. When used concurrently, extremely severe nephropathies are possible. The anaesthetist should be made aware of the use of aminoglycosides before a surgical procedure.

### **Potentially nephrotoxic or ototoxic drugs**

Concurrent administration of gentamicin and other potentially ototoxic or nephrotoxic drugs should be avoided whenever possible. Where co- administration is considered necessary, because of the increased risk of undesired effects, careful monitoring is required of patients being treated concurrently or sequentially with potentially nephrotoxic or ototoxic drugs such as:

- Antibacterials: some cephalosporins notably cephalotin and cephaloridine, colistin, vancomycin, viomycin, other aminoglycosides such as streptomycin
- Antifungals: amphotericin B
- Loop diuretics such as ethacrynic acid and frusemide
- Cytotoxics: cisplatin. It must be noted that the nephrotoxicity of gentamicin can be increased even 3 to 4 weeks after these substances are administered.
- Anti suppressant: ciclosporin

### **Other antibiotics**

A reduction in gentamicin serum half-life has been reported in patients with severe renal impairment receiving carbenicillin concomitantly with gentamicin.

### **Indometacin**

Indometacin possibly increases plasma concentrations of gentamicin in neonates.

### **Oral anticoagulants**

Concurrent use with oral anticoagulants may increase the hypotherbinanaemic effect.

### **Bisphosphonates**

Concurrent use of bisphosphonates may increase the risk of hypocalcaemia.

### **Cholinergics**

Antagonism of effect may occur with concomitant administration of gentamicin with either neostigmine or pyridostigmine.

Concurrent use of botulinum toxin and gentamicin may increase the risk of toxicity due to enhanced neuromuscular block.

## **4.6 Pregnancy and lactation**

### Pregnancy

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There are no adequate data from the use of gentamicin in pregnant women. Studies in animals have shown reproductive toxicity. Gentamicin crosses the placenta. Because of the potential risk of inner ear and renal damage to the fetus, gentamicin should not be used in pregnancy unless in case of a life-threatening indication and if the benefit outweighs the risk.

In case of exposition to gentamicin during pregnancy, monitoring of hearing and renal function of the newborn is recommended.

#### Breast-feeding

Gentamicin is excreted in human breast milk and was detected in low concentrations in serum of breast-fed children. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from gentamicin therapy. Diarrhoea and fungus infection of the mucous membranes could occur in the breast-fed infant, so that nursing might have to be discontinued. The possibility of sensitisation should be borne in mind.

#### **4.7 Effects on ability to drive and use machines**

Caution is advised when driving and using machines in view of the possible undesired effects such as dizziness and vertigo.

#### **4.8 Undesirable effects**

Side-effects include vestibular damage or hearing loss, particularly after exposure to ototoxic drugs or in the presence of renal dysfunction. Nephrotoxicity (usually reversible) and occasionally acute renal failure, hypersensitivity, anaemia, blood dyscrasias, purpura, stomatitis, convulsions and effects on liver function occur occasionally.

Rarely hypomagnesia on prolonged therapy and antibiotic-associated colitis have been reported.

Nausea, vomiting and rash have also been reported.

Central neurotoxicity, including encephalopathy, confusion, lethargy, mental depression and hallucinations, has been reported in association with gentamicin therapy but this is extremely rare.

Peripheral neuropathy - Frequency not known

#### **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**

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### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial for systemic use

ATC code: J01GB03

Gentamicin is an aminoglycoside antibiotic extracted from *Micromonospora purpurea*. It represents a mixture of the structurally very similar homologues gentamicin C1, C1a and C2. The gentamicin homologue C2 is classified as the component with the highest toxicity. The antibacterial activity of gentamicin sulphate is determined both on the basis of units and also on the basis of mass (weight).

#### Mechanism of action:

Gentamicin has bactericidal efficacy both in the proliferation and in the resting stage of bacteria. It forms a bond with the proteins of the 30S subunits of the bacterial ribosomes, which causes “misreading” of the mRNA.

#### PK/PD relationship

The aminoglycosides show a concentration dependent anti-bacterial effect.

Gentamicin and other aminoglycosides show a clear post-antibiotic effect *in vitro* and *in vivo* in most experimental models of infection. Provided sufficiently high doses are administered, these drugs are therefore efficacious against infections with many susceptible micro-organisms even if the concentration in plasma and tissues remains below the MIC during part of the dosage interval. The post-antibiotic effect permits the dosage interval to be extended without loss of efficacy against most Gram-negative bacilli.

#### Mechanism of resistance

Resistance may be due to a failure of permeation, low affinity for the bacterial ribosome or inactivation of gentamicin by microbial enzymes. The emergence of resistance during therapy is unusual.

#### Breakpoints

According to EUCAST, the following limit values apply for gentamicin:

Pathogen	Susceptible	Resistant
Enterobacteriaceae	2 mg/l	> 4 mg/l
<i>Pseudomonas spp.</i>	4 mg/l	> 4 mg/l
<i>Acinetobacter spp.</i>	4 mg/l	> 4 mg/l
<i>Staphylococcus spp.</i>	1 mg/l	> 1 mg/l
<i>Non-species related breakpoints*</i>	2 mg/l	> 4 mg/l

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when

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treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable. Especially in such circumstances, samples should be obtained in order to identify the causal micro-organism and to measure its sensitivity to gentamicin.

<b>Commonly susceptible species (according to EUCAST)</b>
<b>Aerobic Gram-positive micro-organisms</b>
<i>Listeria monocytogenes</i>
<i>Staphylococcus aureus (MSSA)</i>
<b>Aerobic Gram-negative micro-organisms</b>
<i>Campylobacter coli</i>
<i>Campylobacter jejuni</i>
<i>Citrobacter koseri</i>
<i>Enterobacter aerogenes</i>
<i>Enterobacter cloacae</i>
<i>Escherichia coli</i>
<i>Francisella tularensis</i>
<i>Klebsiella oxytoca</i>
<i>Klebsiella pneumoniae</i>
<i>Proteus vulgaris</i>
<i>Salmonella enterica subsp. enterica</i>
<i>Serratia marcescens</i>
<i>Yersinia enterocolitica</i>
<i>Yersinia pseudotuberculosis</i>
<b>Species for which acquired resistance may be a problem</b>
<b>Aerobic Gram-positive micro-organisms</b>
<i>Staphylococcus aureus (MRSA)</i>
<i>Staphylococcus epidermidis</i>
<i>Staphylococcus haemolyticus</i>
<i>Staphylococcus hominis</i>
<b>Aerobic Gram-negative micro-organisms</b>
<i>Acinetobacter spp.</i>
<i>Citrobacter freundii</i>
<i>Morganella morganii</i>
<i>Proteus mirabilis</i>

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<i>Pseudomonas aeruginosa</i>
<b>Inherently resistant organisms</b>
<b>Aerobic Gram-positive micro-organisms</b>
<i>Enterococcus faecalis</i>
<i>Enterococcus faecium</i>
<i>Streptococcus spp.</i>
<b>Aerobic Gram-negative micro-organisms</b>
<i>Burkholderia cepacia</i>
<i>Legionella pneumophila</i>
<i>Stenotrophomonas maltophilia</i>
<b>Anaerobic micro-organisms</b>
<i>Bacteroides spp.</i>
<i>Clostridium difficile</i>
<b>Others</b>
<b>Atypical pathogens</b>
<i>Chlamydia spp.</i>
<i>Chlamydophila spp.</i>
<i>Mycoplasma spp.</i>
<i>Ureaplasma urealyticum</i>

Abbreviations:

MSSA = Methicillin-sensitive *Staphylococcus aureus*,

MRSA = Methicillin-resistant *Staphylococcus aureus*

Infections caused by Streptococci or Enterococci:

Aminoglycosides are suitable combination partners for other antibiotics against Gram-positive cocci. For some indications (endocarditis), synergistic effects with beta-lactams have been described. This synergy is abolished when Streptococci or Enterococci present a high level acquired resistance to gentamicin.

Other notes:

Synergistic effects have been described with acylamino penicillins (e.g. piperacillin) on *Pseudomonas aeruginosa* and with cephalosporins on *Klebsiella pneumoniae*.

## 5.2 Pharmacokinetic properties

### Absorption

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Like all aminoglycoside antibiotics, gentamicin is barely absorbed by healthy intestinal mucosa after oral administration. Therefore therapeutic application is parenteral.

Higher peak and lower trough levels are found when the total daily dose is given as a single daily infusion. When gentamicin is administered by intravenous short infusion of 30 minutes at 4 mg/kg body weight per day in three divided doses, peak and trough gentamicin concentrations measured in adult patients were 4.7 µg/ml and 1.0 µg/ml, respectively. With the same daily dose administered once daily, peak and trough concentrations of 9.5 µg/ml and 0.4 µg/ml were measured.

Therapeutic serum concentrations generally lie between 2 and 8 µg/ml. Therapeutic peak serum concentrations are in the range of 5 – 10 µg/ml for multiple daily dosing and 20 – 30 µg/ml for once daily dosing. Maximum serum concentrations of 10 – 12 µg/ml should not be exceeded when administered conventionally, in several doses per day. Before another dose is administered, the serum concentration when administered conventionally, in several doses per day, should have fallen below 2 µg/ml.

### **Distribution**

The distribution volume of gentamicin is about equivalent to the volume of extracellular water. In the newborn water makes up 70 to 75% of bodyweight, compared with 50 to 55% in adults. The extracellular water compartment is larger (40% of body weight compared with 25% of body weight in adults). Therefore, the volume of distribution of gentamicin per kg bodyweight is affected and decreases with increasing age from 0.5 to 0.7 l/kg for a premature newborn to 0.25 l/kg for an adolescent. The larger volume of distribution per kg bodyweight means that for adequate peak blood concentration a higher dose per kg bodyweight needs to be administered.

The distribution of gentamicin to the individual organs results in varying tissue concentrations; the highest concentrations appear in the renal tissue. Smaller concentrations are found in the liver and gall bladder, the lung and spleen.

Gentamicin crosses the placenta; the foetal concentrations can be 30% of the maternal plasma concentrations. Gentamicin is excreted in small quantities in breast milk (1/3 of the concentration is found here, as in the case of the maternal plasma).

After repeated injection of gentamicin, approximately 50% of the concentrations reached in plasma is measured in the synovial, pleural, pericardial and peritoneal fluid. The penetration of gentamicin into the cerebrospinal fluid is poor in un-inflamed meninges. In inflamed meninges, concentrations reach up to 30% of the concentrations measured in plasma.

Plasma protein binding: less than 10%.

### **Biotransformation**

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Gentamicin is not metabolised in the organism but is excreted unchanged in microbiologically active form.

### **Elimination**

Gentamicin is eliminated unchanged in microbiologically active form principally in the urine by glomerular filtration. The dominant elimination half-life in patients with normal renal function is around 2 – 3 hours. Elderly patients eliminate gentamicin more slowly than younger adults.

### **5.3 Preclinical safety data**

#### **Chronic toxicity**

In studies on chronic toxicity (i.m. application) carried out on various animal species, nephrotoxic and ototoxic effects were observed at high dosages.

#### **Mutagenic and carcinogenic potential**

Gentamicin was not mutagenic in in vitro and in vivo tests. There are no long-term studies on animals on the carcinogenic potential of gentamicin.

#### **Reproductive toxicity**

There is a potential risk of inner ear and renal damage to the fetus as was observed for the class of aminoglycoside antibiotics. Fetal renal abnormalities have been documented in rats and guinea pigs after administration of gentamicin to the dams.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Anhydrous sodium sulfite  
Sodium bisulfite  
Disodium Edetate  
Water for injection

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

Three years.

After first opening: from the microbiological point of view, the product should be used immediately.

After dilution: when diluted with 0.9% sodium chloride or 5% glucose solution, gentamicin is stable for 24 h at 25°C.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately.

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If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

#### **6.4 Special precautions for storage**

Store below 30°C. Do not refrigerate or freeze. Store in the original package in order to protect from light.

For storage conditions after dilution of the medicinal product, see section 6.3.

#### **6.5 Nature and contents of container**

Glass ampoule

#### **6.6 Special precautions for disposal and other handling**

Gentamicin can be diluted with 0.9% sodium chloride or 5% glucose solution.

For single use only

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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