NAME OF THE MEDICINAL PRODUCT

Gentamicin 1 mg/ml solution for infusion
Gentamicin 3 mg/ml solution for infusion

COMPOSITION

1 mg/ml solution for infusion:
1 ml of solution for infusion contains gentamicin sulphate equivalent to 1 mg gentamicin.
1 bottle of 80 ml contains 80 mg of gentamicin.

Excipient with known effect: 283 mg (12 mmol) of sodium (as chloride) per 80 ml bottle.
Excipients: Sodium chloride, water for injections.

3 mg/ml solution for infusion:
1 ml of solution for infusion contains gentamicin sulphate equivalent to 3 mg gentamicin.
1 bottle of 80 ml contains 240 mg of gentamicin.
1 bottle of 120 ml contains 360 mg of gentamicin.

Excipients with known effect: 283 mg (12 mmol) of sodium (as chloride) per 80 ml bottle. 425 mg (18 mmol) of sodium (as chloride) per 120 ml bottle.
Excipients: Disodium edetate, sodium chloride, water for injections

THERAPEUTIC INDICATIONS

For the treatment of severe infections due to bacteria susceptible to gentamicin when less toxic antimicrobial agents are not effective.

Gentamicin 1 mg/ml solution for infusion and Gentamicin 3 mg/ml solution for infusion should for all indications, except complicated urinary tract infections, only be used in combination with other relevant antibiotics (predominantly together with a beta-lactam antibiotic or with an antibiotic effective against anaerobic bacteria).
Under these conditions, Gentamicin 1 mg/ml solution for infusion and Gentamicin 3 mg/ml solution for infusion may be used in complicated and recurrent urinary tract infections; nosocomial lower respiratory tract infections including severe pneumonia; intraabdominal infections including peritonitis; skin and soft tissue infections including severe burns; septicaemia including bacteraemia; treatment of bacterial endocarditis; treatment of surgical infections.

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

CONTRAINDICATIONS

Hypersensitivity to the active substance, other aminoglycosides or to any of the excipients; myasthenia gravis.

UNDESIRABLE EFFECTS

Under certain conditions gentamicin shows ototoxic and/or nephrotoxic effects. Renal impairment is commonly observed in patients treated with gentamicin and is usually reversible upon withdrawal of the drug. In most cases nephrotoxicity is associated with an excessively high dosage or prolonged treatment, pre-existing renal abnormalities or associated with other substances reported to be nephrotoxic.

The adverse reactions considered at least possibly related to treatment are listed below by body system organ class and absolute frequency.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Rare: (≥ 1/10 000 to < 1/1000)
Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

System Organ Class	**Common**	**Uncommon**	**Rare**	**Very rare**	**Not known**
Infections and infestations					Superinfection (caused by gentamicin-resistant bacteria), pseudomembranous colitis
Blood and lymphatic system disorders		Dyscrasia		Thrombocytopaenia, reticulocytopaenia, leukopaenia, eosinophilia, granulocytopaenia, anaemia	

Immune system disorders					Anaphylactic reaction (including anaphylactic shock) and hypersensitivity
Metabolism and nutrition disorders			Hypokalaemia, hypocalcaemia, hypomagnesaemia, pseudo-Bartter syndrome in patients treated with high doses over a long period (more than 4 weeks), loss of appetite, weight loss	Hypophosphataemia	
Psychiatric disorders				Confusion, hallucinations, mental depression	
Nervous system disorders			Polyneuropathies, peripheral paraesthesias	Encephalopathy, convulsions, neuromuscular blockage, dizziness, balance disorder, headache	
Eye disorders				Visual disorders	
Ear and labyrinth disorders				Vestibular damage, hearing loss, Meniére`s disease, tinnitus vertigo	Irreversible hearing loss, deafness
Vascular disorders				Hypotension, hypertension	
Gastrointestinal disorders			Vomiting, nausea, salivation increased, stomatitis		

Hepatobiliary disorders			Aspartate aminotransferase (AST) increased, Alanine aminotransferase (ALT) increased, alkaline phosphatase (ALP) increased, reversible increase of serum bilirubin (all reversible)		
Skin and subcutaneous tissue disorders		Allergic skin exanthema	Skin reddening	Erythema multiforme[1], alopecia	Steven Johnson syndrome, Toxic epidermal necrolysis
Musculoskeletal and connective tissue disorders			Muscle pain (myalgia)	Amyostasia	
Renal and urinary disorders	Renal function impairment		Blood urea nitrogen increased (reversible)	Acute renal failure, hyperphosphaturia, aminoaciduria, Fanconi-like syndrome in patients treated with a prolonged course of high-dose	
General disorders and administration site conditions			Increased body temperature	Pain at injection site	

[1] May occur as hypersensitivity reactions

WARNING

Keep out of the reach and sight of children.
For single use only. Unused solution should be discarded. Only clear solutions free from particles should be used.

NOTE

Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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