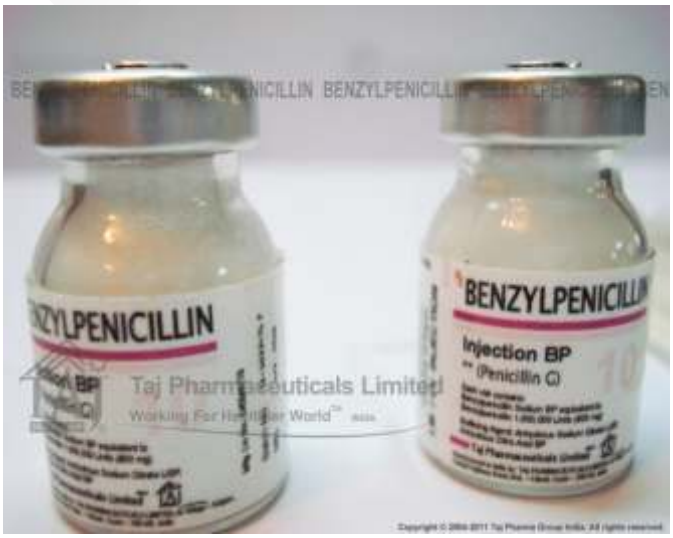
BENZYL PENICILLIN



Active Ingredients:

• BENZYL PENICILLIN 600 mg (1 Mu) INTRAMED Powder for Injection
BENZYL PENICILLIN 3,0 g (5 Mu) INTRAMED Powder for Injection

COMPOSITION:

1.Benzyl penicillin 600 mg per vial, as the sodium salt

2.Benzyl penicillin 3,0 g per vial, as the sodium salt.
Buffered with 3,0% m/m sodium citrate

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins.

PHARMACOLOGICAL ACTION:

The cell walls are essential for normal growth and development of bacteria. Peptidoglycan is the heteropolymeric component of the cell wall providing rigid mechanical stability. The action of the beta-lactam antibiotics is involved in the third stage of cell membrane cross-link formation, namely the transpeptidation reaction. The terminal glycine residue of the pentaglycine bridge is linked to the fourth residue (D-alanine) releasing the fifth residue (also D-alanine) and this step is inhibited by the beta-lactam antibiotics. The transpeptidase is probably acylated by penicillin. Various penicillin binding proteins (transpeptidases and carboxypeptidases) are associated with the bacterial cell membrane and beta-lactam antibiotics bind tightly to them. The penicillin binding proteins vary from one bacterial species to another and in their affinity for different antibiotics. The morphological changes brought about are dependant on the antibiotic, its concentration and the microbe. As the concentration is increased, growth is inhibited, bulges form and lysis follows. Resistant strains (containing no autolysins) will not lysate and different type of antibiotics are to be used.

• Bacterial resistance may be because of:

1)enzymatic structural differences (natural or because of mutation);

2)inability of antibiotic to permeate its site of action;

3)enzymatic destruction by beta lactamases or penicillinases.

Its activity is also influenced by:

a)density of bacterial population and the age of an infection;

b)these antibiotics are most active against bacteria in the logarithmic phase of growth and have little effect on bacteria in the lagphase;

c)bacteria that survive inside viable host cells are protected;

d)low pH or oxygen tension activate the antibiotics.
After intramuscular injection peak plasma concentrations are reached within 15 to 30 minutes. The penicillin G halflife is about 30 minutes. This may be prolonged with Probenecid. Benzyl penicillin is distributed in the body about 50% in the total body water, 90% in the blood is in the plasma and 65% is reversibly bound to plasma albumin. Significant amounts appear in liver, bile, kidney, joint fluid, lymph, intestines and semen. Therapeutically effective concentrations can be attained in the CSF if the meninges are acutely inflamed. It is rapidly excreted by the kidneys.

BENZYL PENICILLIN

INDICATIONS:

Benzyl penicillin is highly active against gram-positive cocci and is similar to that of penicillin V in aerobic gram-positive micro-organisms. It is five to ten times more active against gram-negative micro-organisms.

1. Gram-positive Cocci	Diseases		1st Choice	Dose Mu (Mega-units)	Duration of Therapy
Staphylococcus aureus	Abscesses, Bacteremia, Endocarditis, Pneumonia.	Penicillin G sensitive	Penicillin G	10 to 20 mega-units per day	3 to 5 days
	Meningitis, Osteomyelitis, Cellulitis, Other.	Penicillin G resistant	A Penicillinase resistant Penicillin	.	.
		Methicillin resistant	Vancomycin	.	.
Streptococcus pyogenes	Pharyngitis, Scarlet fever, Otitis media, Sinusitis, Cellulitis, Erysipelas, Pneumonia, Bacteremia, Other systemic infections		Penicillin G	10 to 20 Mu per day in 4 to 6 portions or continuous infusion	2 to 4 weeks
			Penicillin V	500 mg every 6 hours	10 days
Streptococcus (viridans group)	Endocarditis, Bacteremia.		Penicillin G + Streptomycin or Gentamicin	6 to 10 Mu per day -I.V. & Streptomycin 500 mg I.M. twice daily.	2 weeks
r				Some prefer Pen. G. alone	4 weeks
Streptococcus agalactia (B group)	Septicemia Meningitis		Ampicillin or Penicillin G & Amino-glycoside	150 000 to 250 000 units per kg per day parenterally	
Streptococcus faecalis (enterococcus)	Endocarditis		Penicillin G & Gentamicin or Streptomycin	20 Mu daily -I.V. & Streptomycin 500 mg I.M. every 12 hours or Gentamycin 1 mg/kg every 8 hours	4 to 6 weeks
	Urinary tract infection, Bacteremia		Ampicillin or Penicillin G	10 to 20 Mu I.V.	2 weeks
Streptococcus bovis	Endocarditis, Urinary-tract infection, Bacteremia.		Penicillin G & Streptomycin or Gentamicin	10 to 20 Mu I.V.	2 to 4 weeks
Streptococcus (anaerobic species)	Bacteremia, Endocarditis, * Brain and other abscesses, Sinusitis.		Penicillin G	10 to 20 Mu I.V. *20 Mu daily & Chloramphenicol 2 - 4 g daily I.V. or metronidazole 2 - 4 g daily I.V.	At least 2 weeks
Streptococcus pneumoniae (pneumococcus)	Pneumonia, Endocarditis, Arthritis Sinusitis, Otitis.		Penicillin G	10 to 20 Mu daily I.V.	At least 2 weeks
				If there is bone infection, prolong therapy	To at least 4 weeks
	Meningitis		Penicillin G	20 to 40 Mu daily by constant I.V. drip or divided into boluses every 2 - 3 hours	14 days
2. Gram-negative Cocci	**Diseases**		**1st Choice**	**Dose**	**Duration of therapy**
Neisseria gonorrhoea (gonococcus)	Genital infections	Penicillin sensitive	Ampicillin or Amoxicillin Penicillin G A tetracycline	Only longacting Pen. G plus Probenecid	
		Penicillinase producing	Spectinomycin		
	Arthritis-dermatitis syndrome		Ampicillin or Amoxicillin Penicillin G	10 Mu daily -I.V	3 days
				followed by ampicillin or Amoxicillin given orally	5 - 7 days
Neisseria meningitidis	Meningitis, Bacteremia.		Penicillin G	20-24 Mu daily by constant I.V. drip or divided into boluses given every 2 - 3 hours	14 days

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3. Gram-positive Bacilli	Disease	1st Choice	Dose Mu (million units)	Duration of therapy
Bacillus anthracis	"Malignant pustule", Pneumonia	Penicillin G	10 to 20 Mu	12 days
Corynebacterium diphtheria	Pharyngitis, Laryngotracheitis, Pneumonia, Other local lesions	Penicillin G (Eliminates the carrier state)	2-3 Mu daily in divided doses	10-12 days
	Carrier State	Erythromycin	.	.
Corynebacterium aerobic and anaerobic (diphtheroids)	Endocarditis, Infected foreign bodies.	Penicillin G and an Aminoglycoside. Vancomycin	2 to 3 Mu dailyin divided doses	10-12 days
Listeria monocytogenes	Meningitis, Bacteremia *Endocarditis	Ampicillin or Penicillin G and an Aminoglycoside	15 to 20 Mu daily parenterally	At least 2 weeks * not less than 4 weeks
Erysipelothrix rhusiopathiae	Erysipeloid	Penicillin G	When endocarditis present 2-20 Mu daily	4 to 6 weeks
Clostridium perfrigens and other species	Gas Gangrene	Penicillin G	10-20 Mu daily, parenterally 300 mg every 6 hours in prophylactic	7 days
Clostridium tetani	Tetanus	Penicillin G	To eradicate vegetative bacterial forms	.
4. Gram-negative Bacilli	.	.	.	.
Pasturella multocida	Abscesses, Wound infection (animal bites), Bacteremia, Meningitis.	Penicillin G	4-6 Mu daily parenterally	At least 2 weeks
Bacteroids species (oral, pharyngeal)	Oral disease, Sinusitis, Brain abscess, Lung abscess.	Penicillin G Clindamycin	.	.
Fusobacterium nucleatum	Ulcerative pharyngitis, Lung abscess, Empyema, Genital infections, Gingivitis	Penicillin G Clindamycin Penicillin V	500 mg every 6 hours	5 days
Streptobacillus moniliformis	Bacteremia, Arthritis, Endocarditis, Abscesses.	Penicillin G	12-15 Mu per day given parenterally	3 to 4 weeks
5. Spirochetes Treponema pallidum	Syphilis, primary, secondary or latent	Penicillin G	20 Mu daily I.V.	14 days
			followed by 2,4 Mu benzathine Penicillin weekly.	3 weeks
			Infants50 000 units per kg in 2 divided doses per day	at least 10 days
Treponema pertenue	Yaws	Penicillin G	.	.
Leptospira	Weil's disease, Meningitis.	Penicillin G Penicillin V or Tetracycline	Oral Penicillin 500 mg every 6 hrs	5 days
6. Actinomycetes Actinomyces israelii	Cervicofacial, abdominal, thoracic, and other lesions	Penicillin G	10 to 20 Mu daily - I.V.	6 weeks

• CONTRA-INDICATIONS:

Must not be administered to patients who are allergic to penicillins.

• WARNINGS:

May cause death when administered to patients sensitive to penicillins. Do not add to containers of infusions containing dextrose. It may be piggy-backed via the same administration set.

• DOSAGE AND DIRECTIONS FOR USE:

See table under indications. It should be limited to use by in with other drugs as it is incompatible with many. Children should receive 100 000 to 250 000 units/kg per day in 4 to 6 portions. Newborns up to 1 week - 50 000 to 150 000 units/kg/day in 2 to 3 portions. Dilute with WATER FOR INJECTIONS. Use only freshly prepared solutions. Discard unused portion.

BENZYL PENICILLIN

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	Carrier State	Erythromycin	.	.
Corynebacterium aerobic and anaerobic (diphtheroids)	Endocarditis, Infected foreign bodies.	Penicillin G and an Aminoglycoside. Vancomycin	2 to 3 Mu dailyin divided doses	10-12 days
Listeria monocytogenes	Meningitis, Bacteremia *Endocarditis	Ampicillin or Penicillin G and an Aminoglycoside	15 to 20 Mu daily parenterally	At least 2 weeks * not less than 4 weeks
Erysipelothrix rhusiopathiae	Erysipeloid	Penicillin G	When endocarditis present 2-20 Mu daily	4 to 6 weeks
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Pasturella multocida	Abscesses, Wound infection (animal bites), Bacteremia, Meningitis.	Penicillin G	4-6 Mu daily parenterally	At least 2 weeks
Bacteroids species (oral, pharyngeal)	Oral disease, Sinusitis, Brain abscess, Lung abscess.	Penicillin G Clindamycin	.	.
Fusobacterium nucleatum	Ulcerative pharyngitis, Lung abscess, Empyema, Genital infections, Gingivitis	Penicillin G Clindamycin Penicillin V	500 mg every 6 hours	5 days
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5. Spirochetes Treponema pallidum	Syphilis, primary, secondary or latent	Penicillin G	20 Mu daily I.V.	14 days
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• CONTRA-INDICATIONS:

Must not be administered to patients who are allergic to penicillins.

• WARNINGS:

May cause death when administered to patients sensitive to penicillins. Do not add to containers of infusions containing dextrose. It may be piggy-backed via the same administration set.

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600 mg (1 Mega-unit) Vial		3 g (5 Mega-unit) Vial	
Concentration	mL solvent	Concentration	mL solvent
100 000 units/mL	9,6 mL	250 000 units/ mL	17,9 mL
200 000 units/mL	4,6 mL	400 000 units/ mL	10,4 mL
250 000 units/mL	3,6 mL	500 000 units/ mL	7,9 mL
500 000 units/2 mL	3,6 mL	1 000 000 units/ mL	2,9 mL
1 000 000 units/mL	0,6 mL	2 000 000 units/5 mL	10,4 mL
1 000 000 units/5 mL	4,6 mL	5 000 000 units/5 mL	2,9 mL
		5 000 000 units/10 mL	7,9 mL

BENZYL PENICILLIN

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

When administered to a hypersensitive patient, anaphylactic shock with collapse and sometimes death may occur within minutes. A generalised sensitivity reaction can occur within 1 to 3 weeks with urticaria, fever, eosinophilia, joint pains, angioneurotic oedema, erythema multiforme and exfoliative dermatitis, although an accelerated urticarial reaction can develop within hours. Glossitis, angular and aphtous stomatitis, and darkening of the tongue are liable to follow the use of penicillin.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Convulsions and other signs of toxicity to the central nervous system may occur with very high doses of benzyl penicillin particularly when administered intravenously to infants, the elderly, to patients with renal failure, or when administered intrathecally in doses above 12 mg.
Nephrotoxicity has occurred in some patients with diminished renal function given large doses of benzyl penicillin. Acute interstitial nephritis, a hypersensitivity reaction, has also been reported. Disturbances of blood electrolytes may follow the administration of large doses of the potassium and sodium salts of benzyl penicillin.

Treatment:

When cutaneous reactions occur, they may subside spontaneously with a few hours or days when penicillin is withdrawn. Control of reactions may be attempted by the administration of antihistamines or, should there be no response with corticosteroids. Desensitisation has been attempted when treatment with penicillin has been considered essential. At the first sign of an immediate reaction to penicillin treatment, 0,3 to 1 mL of Adrenaline Injection should be given intramuscularly (or in severe cases 0,2 mL well diluted intravenously) followed by a further dose if no improvement occurs. This should be followed by an antihistamine, such as diphenhydramine or chlorpheniramine, given parenterally and a corticosteroid given intravenously. If bronchospasm is severe, aminophylline (250 mg in 10 mL) may be given intravenously. Assisted respiration is necessary if there is upper airway obstruction and plasma or suitable electrolyte solutions should be given intravenously if circulatory failure occurs. Urticaria and joint pains, if severe, may be treated with corticosteroids by mouth.

• IDENTIFICATION:

Sterile soluble white powder in a clear glass vial.

• PRESENTATION:

Benzyl Penicillin 600 mg (1 Mu) Intramed: In boxes of 100 vials each
Benzyl Penicillin 3 g (5 Mu) Intramed: In boxes of 50 vials each

Benzyl Penicillin 600 mg (1 Mu) Injection

STORAGE INSTRUCTIONS:

Store dry, below 25°C. KEEP OUT OF REACH OF CHILDREN.
Discard any unused portion.

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Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries. www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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