Julmentin

Clavulanate – potentiated Amoxicillin
For intravenous use

Julmentin is a white to off-white powder, which makes a pale, straw colored solution when reconstituted in water. A transient pink coloration may appear during reconstitution.

Composition

Julmentin 0.6g Injection:	Each vial contains 500mg amoxicillin as amoxicillin sodium and 100mg clavulanic acid as potassium clavulanate.
Julmentin 1.2g Injection:	Each vial contains 1g amoxicillin as amoxicillin sodium and 200mg clavulanic acid as potassium clavulanate.

Properties

Julmentin is a combination of an aminopenicillin, amoxicillin, and a progressive and irreversible beta-lactamase inhibitor, clavulanic acid.
Amoxicillin has a broad-spectrum bactericidal activity against many Gram-positive and Gram-negative microorganisms, however, it is susceptible to degradation by beta-lactamases. The combination of amoxicillin with clavulanic acid in **Julmentin**; therefore, protects amoxicillin from inactivation by beta-lactamases and effectively extends its spectrum of activity. **Julmentin** will not only eliminate primary pathogens but also will not be inactivated by non-pathogenic β-lactamase producing organisms at the site of infection.

Bacteriology

Julmentin is effective against the following microorganisms, including ß-lactamase–producing strains resistant to ampicillin and amoxicillin, both in hospital and general practice environment:

Gram - Positive :

Aerobes

Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Bacillus antharacis, Streptococcus pneumoniae, Streptococcus viridans, Streptococcus faecalis, Streptococcus agalactiae, Corynebacterium spp., and *Listeria monocytogenes.*

Anaerobes

Clostridium spp., Peptococcus spp., and *Peptostreptococcus spp.*

Gram - Negative :

Aerobes

Escherichia coli, Proteus mirabilis, Proteus vulgaris, Klebsiella spp., Salmonella spp., Shigella spp., Enterobacter spp., Vibrio cholerae, Campylobacter jejuni, Helicobacter pylori, Yersinia enterocolitica, Brucella spp., Neisseria meningitidis, Neisseria gonorrhoeae, Haemophilus influenzae, Haemophilus ducreyi, Branhamella catarrhalis, Bordetella pertussis, Gardnerella vaginalis, Legionella spp., and *Pasteurella multocida.*

Anaerobes

Bacteroides spp. including *Bacteroides fragilis.*

Indications

Julmentin is indicated for the treatment of the following bacterial infections:

- Upper respiratory tract infections: e.g., sinusitis, tonsillitis, otitis media.
- Lower respiratory tract infections: e.g., acute and chronic bronchitis, lobar and bronchopneumonia, empyema, lung abscess.
- Skin and soft tissue Infections: e.g., boils/abscesses, cellulitis, wound infections, intra-abdominal sepsis.
- Genito-urinary tract infections: e.g., cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, pelvic infections, chancroid, gonorrhoea.
- Other infections: e.g., osteomyelitis, septicaemia, peritonitis, post-operative infections.

Julmentin is also indicated for prophylaxis against infections which may be associated with major surgical procedures such as gastrointestinal, pelvic, head and neck, cardiac, renal, biliary tract and joint replacement surgery.

Dosage

Julmentin may be given either by intravenous injection or by intermittent infusion.

Adults and Children over 12 years :

Usually, 1.2g every 8 hours, increasing the frequency to 6 hourly intervals in severe infections. Maximum adult daily dosage is 7.2g and the maximum single dose is 1.2g.

Children under 12 years :

3 *months* – 12 *years:*	Usually 30mg/kg **Julmentin** infusion every 8 hours, or every 6 hours in severe infections.
0 – 3 *months:*	30mg/kg every 12 hours in premature and full term infants during the early neonatal period, increasing to 8 hourly intervals thereafter.

Note :

- Each 30mg **Julmentin** contains 25mg amoxicillin and 5mg clavulanic acid.
- Therapy can be started parenterally and continued with an oral preparation.
- Treatment with **Julmentin** should not extend beyond 14 days without review.

Dosage for Surgical Prophylaxis :

Surgical prophylaxis with **Julmentin** should aim to protect the patient for the period of risk of infection. Procedures lasting for less than one hour are successfully covered in adults by administering 1.2g **Julmentin** at induction of anaesthesia. Longer operations require subsequent doses of 1.2g **Julmentin** (up to four doses in 24 hours) and this regimen can be continued for several days if the procedure has significantly increased the risk of infection. Clear clinical signs of infection at operation will require a normal course of intravenous or oral **Julmentin** therapy post-operatively.

Dosage in Impaired Renal Function :

A recommended regimen for adult is as follows:

Creatinine Clearance (mL/min)	Julmentin Dose
> 30	No change in dosage.
10-30	Initially, 1.2g IV then, 0.6g IV 12 hourly.
< 10	Initially, 1.2g IV then, 0.6g IV 24 hourly.

Note :

- Dialysis decreases serum concentrations of **Julmentin** and an additional 0.6g IV dose may need to be given during dialysis and at the end of dialysis.
- Similar reductions in dosage should be made for children.

Reconstitution and Administration

Julmentin may be administered either by intravenous injection or by intermittent infusion. It is not suitable for intramuscular administration.
For reconstitution, add 10mL or 20mL of sterile Water for Injection B.P. to the contents of 0.6g vial or 1.2g vial respectively.
The stability of **Julmentin** solution is concentration dependent, thus for:

Intravenous Injection:

Julmentin should be used immediately upon reconstitution and given by slow intravenous injection over a period of 3-5 minutes. **Julmentin** may be injected directly into a vein or via a drip tube.

Intravenous Infusion :

Julmentin may be infused in Water for Injection B.P or Sodium Chloride Intravenous Injection B.P (0.9% w/v). Add 0.6g reconstituted solution to 50mL infusion fluid or 1.2g reconstituted solution to 100mL infusion fluid. Infuse over 30-40 minutes immediately after reconstitution. Any residual antibiotic solutions should be discarded.

Stability in IV Fluid

Intravenous infusions of **Julmentin** may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature 25°C in the recommended volumes of the following infusion fluids. If reconstituted and maintained at room temperature, infusions should be completed within the times stated.
Reconstituted solutions should not be frozen.

Intravenous Infusion Fluids	Stability Period at 25°C
Water for Injection B.P.	4 hours
Sodium Chloride Intravenous Infusion B.P (0.9% w/v)	4 hours
Sodium Lactate Intravenous Infusion B.P. (one-sixth molar)	4 hours
Compound Sodium Chloride Intravenous Infusion B.P. (Ringer's Solution)	3 hours
Compound Sodium Lactate Intravenous Infusion B.P. (Ringer-Lactate Solution: Hartmann's Solution)	3 hours
Potassium Chloride and Sodium Chloride Intravenous Infusion B.P.	3 hours

Julmentin is less stable in infusions containing glucose, dextran and bicarbonate. Therefore, the reconstituted solutions of Julmentin should not be added to such infusions but may be injected into the drip tubing over a period of 3-4 minutes.
For storage at 5°C, the reconstituted solution should be added to pre-refrigerated infusion bags which can be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperature.

Intravenous Infusion Fluids	Stability Period at 5°C
Water for Injections B.P.	8 hours
Sodium Chloride Intravenous Infusion B.P (0.9% w/v)	8 hours

Julmentin should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.
If Julmentin is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in syringe, intravenous fluid container, or giving set because loss of activity of the aminoglycoside can occur under these conditions.

Contraindications

A history of allergic reactions to any penicillin is a contraindication.

Precautions

Patients with a history of sensitivity to cephalosporins or even to multiple allergens are more likely to experience hypersensitivity reactions to Julmentin.
Changes in liver function tests have been observed in some patients receiving Julmentin. The clinical significance of these changes is uncertain but intravenous Julmentin should be used with care in patients with evidence of severe hepatic dysfunction.
In patients with impaired renal function Julmentin dosage should be adjusted as recommended in the "Dosage" section.
As with other drugs, Julmentin should not be used during pregnancy unless it is clearly needed. Caution should be exercised when Julmentin is given to nursing mothers since it is excreted in the milk.

Side Effects

Julmentin is generally well tolerated. Side effects are uncommon and mainly of a mild and transietary nature.
The most frequently reported side effects include mild gastrointestinal reactions such as diarrhea, pseudomembranous colitis, indigestion, nausea, vomiting and candidiasis.
Urticarial and erythematous rashes sometimes occur but their incidence has been particularly low in clinical trials. An urticarial rash suggests penicillin hypersensitivity and treatment should be discontinued. Erythematous rashes are frequently mild and transient but may be severe when associated with infectious mononucleosis, in which case treatment should be discontinued.
Moderate increase in serum transaminase levels is less frequently reported.
Phlebitis at the site of injection has also been reported.

Overdosage

Problems of overdosage with Julmentin are unlikely to occur; if encountered they may be treated symptomatically. Julmentin may be removed from the circulation by haemodialysis.

Drug Interactions

Julmentin should not be co-administered with disulfiram.
The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes.
Probenecid decreases the renal tubular secretion of amoxicillin.

Presentation

Julmentin 0.6g Injection: Sterile powder for injection is available in vial containing 500mg of amoxicillin sodium and 100mg of potassium clavulanate.

Julmentin 1.2g Injection: Sterile powder for injection is available in vial containing 1g of amoxicillin sodium and 200mg of potassium clavulanate.

**Store at room temperature not exceeding 25°C, away from heat and light.*

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. (971) 800-4994

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