

P^rCEFTRIAXONE SODIUM FOR INJECTION BP (sterile ceftriaxone sodium)

250 mg, 500 mg, 1 g, 2 g and 10 g ceftriaxone per vial Antibiotic

ACTION

In vitro studies indicate that the bactericidal action of ceftriaxone results from the inhibition of cell-wall synthesis. In *E. coli*, ceftriaxone showed a high affinity for penicillin binding proteins (PBP) 1a and 3 and a moderate affinity for 1b and 2. In *H. influenzae*, the highest affinity was shown for PBP 4 and PBP 5. The binding affinity to PBP 4 was 35-fold that of PBP 3, 10-fold that of PBP 2 and approximately 100-fold that of PBP 1. The morphological changes resulting from the PBP binding include filament formation or cell wall and septal thickening, and then cell lysis.

INDICATIONS AND CLINICAL USES

The treatment of the following infections when caused by susceptible strains of the designated micro-organisms:

Lower Respiratory tract infections caused by *E. coli*, *H. influenzae*, *K. pneumoniae* and species, *Staph. aureus*, *Strep. pneumoniae* and species (excluding enterococci).

Urinary tract infections (complicated and uncomplicated) caused by *E. coli*, Klebsiella species, *P. mirabilis* and *P. vulgaris*.

Bacterial Septicemia caused by *E. coli*, *H. influenzae*, *K. pneumoniae*, *Staph. aureus* and *Strep. pneumoniae* (excluding enterococci).

Skin and Skin Structure Infections caused by *K. pneumoniae* and species, *P. mirabilis*, *Staph. aureus*, *Staph. epidermidis* and *Streptococcus* species (excluding enterococci).

Bone and Joint Infections caused by *Staph. aureus*, *Strep. pneumoniae* and *Streptococcus* species (excluding enterococci).

Intra-Abdominal Infections caused by *E. coli* and *K. pneumoniae*.

Meningitis caused by *H. influenzae*, *N. meningitidis* and *Strep. pneumoniae*. Ceftriaxone Sodium for Injection BP (ceftriaxone sodium) should not be used for the treatment of meningitis caused by *L. monocytogenes*.

Uncomplicated Gonorrhoea (cervical/urethral, pharyngeal and rectal) caused by *N. gonorrhoeae* (penicillinase and nonpenicillinase producing strains).

Susceptibility Testing: Specimens for bacteriologic culture should be obtained prior to therapy in order to identify the causative organisms and to determine their susceptibilities to ceftriaxone. Therapy may be instituted before results of susceptibility testing are known. However, modification of the treatment may be required once these results become available.

Prophylaxis: The preoperative administration of a single 1 g dose of Ceftriaxone Sodium for Injection BP may reduce the incidence of postoperative infections in patients undergoing vaginal or abdominal hysterectomy, coronary artery bypass surgery, or in patients at risk of infection undergoing biliary tract surgery. If signs of post surgical infection should appear, specimens for culture should be obtained for identification of the causative organism(s) so that the appropriate therapy may be instituted.

CONTRAINDICATIONS

Ceftriaxone Sodium for Injection BP (ceftriaxone sodium) is contraindicated in patients with known hypersensitivity to ceftriaxone sodium or any component of the container, other cephalosporins, or penicillins (see **WARNINGS**).

Hypербilirubinemic neonates and preterm neonates should not be treated with ceftriaxone. *In vitro* studies have shown that ceftriaxone can displace bilirubin from its binding to serum albumin, leading to a possible risk of bilirubin encephalopathy in these patients (see **PRECAUTIONS**).

Ceftriaxone Sodium for Injection BP is contraindicated in neonates (\leq 28 days old) if they require (or are expected to require) treatment with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition because of the risk of precipitation of ceftriaxone-calcium (see **WARNINGS**, **PRECAUTIONS**, **ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION**).

WARNINGS

Hypersensitivity

Before therapy with Ceftriaxone Sodium for Injection BP (ceftriaxone sodium) is instituted, careful inquiry should be made concerning previous hypersensitivity reactions to ceftriaxone, other cephalosporins, penicillins or other allergens. Ceftriaxone Sodium for Injection BP should only be administered with caution to any patient who has demonstrated any form of allergy particularly to drugs. As with other cephalosporins, anaphylactic reactions with fatal outcome have been reported, even if a patient is not known to be allergic or previously exposed. Ceftriaxone Sodium for Injection BP should be administered with caution to patients with type I hypersensitivity reaction to penicillin. Cross-hypersensitivity among β -lactam antibiotics have been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction occurs, the administration of Ceftriaxone Sodium for Injection BP should be discontinued and appropriate therapy instituted (see **CONTRAINDICATIONS** and **ADVERSE REACTIONS**).

Hemolytic Anemia

CEFTRIAXONE SODIUM FOR INJECTION BP SHOULD NOT BE USED IN PATIENTS WITH A HISTORY OF CEPHALOSPORIN-ASSOCIATED HEMOLYTIC ANEMIA SINCE THE RECURRENCE OF HEMOLYSIS IS MUCH MORE SEVERE.

An immune mediated hemolytic anemia has been observed in patients receiving cephalosporin class antibacterials, including Ceftriaxone Sodium for Injection BP. Severe cases of hemolytic anemia, including fatalities, have been reported in both adults and children. If a patient develops anemia anytime during, or within 2-3 weeks subsequent to the administration of Ceftriaxone Sodium for Injection BP, the diagnosis of a cephalosporin-associated anemia should be considered and the drug discontinued until the etiology is determined.

Patients who receive prolonged or frequent courses of Ceftriaxone Sodium for Injection BP may benefit from periodic monitoring for signs and symptoms of hemolytic anemia, including measurement of haematological parameters or drug-induced antibody testing, where appropriate (see **ADVERSE REACTIONS**).

Clostridium Difficile-Associated Disease

Clostridium difficile-associated disease (CDAD) has been reported with use of many antibacterial agents, including Ceftriaxone Sodium for Injection BP. CDAD may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea, or symptoms of colitis, pseudomembranous colitis, toxic megacolon, or perforation of colon subsequent to the administration of any antibacterial agent. CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

Treatment with antibacterial agents may alter the normal flora of the colon and may permit overgrowth of *Clostridium difficile*. *Clostridium difficile* produces toxins A and B, which contribute to the development of CDAD. CDAD may cause significant morbidity and mortality. CDAD can be refractory to antimicrobial therapy.

If the diagnosis of CDAD is suspected or confirmed, appropriate therapeutic measures should be initiated. Mild cases of CDAD usually respond to discontinuation of antibacterial agents not directed against *Clostridium difficile*. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial agent clinically effective against *Clostridium difficile*. Surgical evaluation should be instituted as clinically indicated, as surgical intervention may be required in certain severe cases (see **ADVERSE REACTIONS**).

Interaction with Calcium-Containing Products

Do not use diluents containing calcium, such as Ringer’s solution or Hartmann’s solution, to reconstitute Ceftriaxone Sodium for Injection BP vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when Ceftriaxone Sodium for Injection BP is mixed with calcium-containing solutions in the same IV administration line. Ceftriaxone Sodium for Injection BP must not be administered simultaneously with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, Ceftriaxone Sodium for Injection BP and calcium-containing solutions may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid. *In vitro* studies using adult and neonatal plasma from umbilical cord blood demonstrated that neonates have an increased risk of precipitation of ceftriaxone-calcium (see **CONTRAINDICATIONS**, **ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION**).

Though no reports of intravascular calcium-ceftriaxone precipitates have been reported in other than neonatal patients treated with ceftriaxone and calcium-containing intravenous products, caution is nevertheless warranted during intravenous treatment (see **INCOMPATIBILITY**).

There have been reports of sonographic abnormalities in the gallbladder of patients treated with Ceftriaxone Sodium for Injection BP; some of these patients also had symptoms of gallbladder disease. These abnormalities appear on sonography as an echo without acoustical shadowing suggesting sludge or as an echo with acoustical shadowing which may be misinterpreted as gallstones. The chemical nature of the sonographically-detected material has been determined to be predominantly a ceftriaxone-calcium salt. The condition appears to be transient and reversible upon discontinuation of Ceftriaxone Sodium for Injection BP and institution of conservative management. Therefore, Ceftriaxone Sodium for Injection BP should be discontinued in patients who develop signs and symptoms suggestive of gallbladder disease and/or the sonographic findings described above. The effect of pre-existing gallbladder disease is not known.

Cases of pancreatitis, possibly of biliary obstruction etiology, have been rarely reported in patients treated with Ceftriaxone Sodium for Injection BP. Most patients presented with risk factors for biliary stasis and biliary sludge, e.g. preceding major therapy, severe illness and total parenteral nutrition. A trigger or cofactor role of Ceftriaxone Sodium for Injection BP -related biliary precipitation can not be ruled out.

Ceftriaxone may cause renal lithiasis through precipitation of calcium ceftriaxonate. When using this product in subjects with hypercalciuria or a history of renal lithiasis, benefit must be weighed against risk. Very rare cases of nephrolithiasis (renal precipitation) have been reported, mostly in children older than 3 years and who have been treated with either high daily doses (e.g. \geq 80 mg/kg/day) or total doses exceeding 10 grams and presenting other risk factors (e.g. fluid restrictions, confinement to bed, etc.). This event may be symptomatic, may lead to renal insufficiency, and appears to be reversible upon discontinuation of Ceftriaxone Sodium for Injection BP.

Sonography for biliary sludge or renal lithiasis is recommended in cases of right hypochondrial and/or abdominal pain. Ceftriaxone Sodium for Injection BP treatment should be withdrawn to allow signs and symptoms to resolve.

PRECAUTIONS

General

Alterations in prothrombin time (see **ADVERSE REACTIONS**) and hypoprothrombinemia have occurred rarely in patients treated with Ceftriaxone Sodium for Injection BP (ceftriaxone sodium). Patients with impaired vitamin K synthesis or low vitamin K stores (e.g. chronic hepatic disease and malnutrition) may require monitoring of hematology and coagulation parameters during Ceftriaxone Sodium for Injection BP treatment.

Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during treatment.

Prolonged treatment with Ceftriaxone Sodium for Injection BP may result in overgrowth of non-susceptible organisms and organisms initially sensitive to the drug. Development of resistant organisms during the administration of ceftriaxone sodium in clinical trials has been observed in 6% of the 94 patients infected with *P. aeruginosa*, in 33% of 3 patients infected with Citrobacter species and in 10% of the 10 patients infected with Enterobacter species. If superinfection occurs, appropriate measures should be taken.

Ceftriaxone Sodium for Injection BP should be administered with caution to individuals with a history of gastrointestinal disease, particularly colitis.

Renal and Hepatic Impairment

Although transient elevations of BUN and serum creatinine have been observed in clinical studies, there is no other evidence that Ceftriaxone Sodium for Injection BP, when administered alone, is nephrotoxic.

In severe renal impairment (creatinine clearance of less than 10 mL/min), periodic monitoring of serum ceftriaxone concentrations is recommended. The maximum daily dose should not exceed 2 g. In severe renal impairment associated with clinically significant hepatic impairment, close monitoring of serum ceftriaxone concentrations, at regular intervals, is recommended. If there is evidence of accumulation, dosage should be decreased accordingly.

Interactions

Interactions between Ceftriaxone Sodium for Injection BP and other drugs have not been fully evaluated.

Pregnancy

The safety of Ceftriaxone Sodium for Injection BP in the treatment of infections during pregnancy has not been established. Ceftriaxone Sodium for Injection BP should only be used during pregnancy if the likely benefit outweighs the potential risk to the fetus and/or the mother. Ceftriaxone has been detected in the umbilical cord blood, amniotic fluid and placenta. At parturition, 1 hour after a 2 g I.V. dose of ceftriaxone sodium, average ceftriaxone concentrations in maternal serum, umbilical cord serum, amniotic fluid, and placenta were 106 \pm 40 μ g/mL, 19.5 \pm 11.5 μ g/mL, 3.8 \pm 3.2 μ g/mL and 20.9 \pm 4.4 μ g/g.

Nursing Mothers

Ceftriaxone is excreted in human milk at low concentrations, (e.g., the peak concentration of total drug in milk ranged between 0.45 to 0.65 μ g/mL, approximately five hours after the administration of 1 g I.V. or I.M.). The clinical significance of this is unknown, therefore, caution should be exercised when Ceftriaxone Sodium for Injection BP is administered to a nursing mother.

Neonates

The safety of Ceftriaxone Sodium for Injection BP in neonates (birth to one month of age) has not been established. *In vitro* studies have shown that ceftriaxone can displace bilirubin from serum albumin. Ceftriaxone Sodium for Injection BP should not be used in neonates (especially prematures), at risk of developing bilirubin encephalopathy (see **CONTRAINDICATIONS**).

Elderly Patients

The elimination of ceftriaxone may be reduced in elderly patients possibly due to impairment of both renal and hepatic function.

Drug-Laboratory Test Interactions

Ceftriaxone may interfere with urine glucose determinations utilizing the copper-reduction test (Clinitest), but not utilizing the glucose-oxidase test (Diastix or Tes Tape). In patients treated with Ceftriaxone Sodium for Injection BP the Coombs' test may rarely become false-positive; and Ceftriaxone Sodium for Injection BP , like other antibiotics, may result in false-positive tests for galactosemia.

ADVERSE REACTIONS

During clinical trials and post-marketing experience with ceftriaxone sodium the following adverse reactions have been observed:

Clinical Adverse Experiences

Dermatological: Rash (1.3%); exanthema, allergic dermatitis and pruritis (0.1 – 1.0%); urticaria (post-marketing reports). Isolated cases of severe cutaneous adverse reactions (erythema multiforme, Stevens Johnson Syndrome, or Lyell’s Syndrome/toxic epidermal necrolysis) have also been reported.

Hematological: Anemia (0.1 – 1.0%); auto-immune hemolytic anemia and serum sickness (<0.1%); immune hemolytic anemia (post-marketing reports – see **WARNINGS** for more information on hemolytic anemia); granulocytopenia (post-marketing reports). Isolated cases of agranulocytosis (<500/mm³) have been reported, most of them after 10 days of treatment and following total doses of 20 g or more.

Hepatic: Jaundice, reports (in asymptomatic and symptomatic patients) of ultrasonographic shadows suggesting precipitations in the gallbladder and reports of gallbladder sludge (< 0.1%).

Urogenital: Moniliasis and vaginitis (0.1 – 1.0%); oliguria and nephrolithiasis (post-marketing reports).

Gastrointestinal: Diarrhea (3.3%), nausea, vomiting, dysgeusia and gastric pain (0.1 – 1.0%); abdominal pain, colitis, flatulence, dyspepsia, pseudomembranous colitis and stomatitis (< 0.1%); glossitis (post-marketing reports).

Neurological: Dizziness and headache (0.1 – 1.0%); ataxia and paresthesia (< 0.1%).

Miscellaneous: Fever, chills, diaphoresis, malaise, burning tongue, flushing, edema and anaphylactic shock (0.1 – 1.0%); bronchospasm, palpitations and epistaxis (< 0.1%); glottic/laryngeal edema (post-marketing reports).

Local Reactions at Injection Site: Pain (9.4%); induration and tenderness (1 – 2%); phlebitic reactions (0.1 – 1.0%); thrombophlebitis (< 0.1%).

- ^a Pain on intramuscular injection is usually mild and less frequent when the drug is administered in sterile 1% Lidocaine solution.

Laboratory Abnormalities

Hematology: Eosinophilia (4.6%), thrombocytosis (5.1%), leukopenia (2.0%); neutropenia, lymphopenia, thrombocytopenia, increase or decrease in hematocrit, prolongation of prothrombin time and decrease in hemoglobin (0.1 – 1.0%); leucocytosis, lymphocytosis, monocytosis, basophilia and decrease in prothrombin time (< 0.1%). (See **PRECAUTIONS** for information on alterations in prothrombin time.)

Hepatic: Increase in AST (SGOT) (4.0%)^b; ALT (SGPT) (4.8%)^b; increase in alkaline phosphatase (1.0%); increase in bilirubin (0.1 – 1.0%).

Urinary: Increase in BUN (1.1%)^c; increase in creatinine, erythrocyturia, proteinuria and presence of casts in urine (0.1 – 1.0%); glycosuria (< 0.1%).

- ^b Incidence is more frequent in patients less than one year old.
- ^c Incidence is more frequent in patients less than one year old and over 50 years old.

Post-Market Adverse Drug Reactions

A small number of cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving ceftriaxone sodium and calcium-containing fluids. In some of these cases, the same intravenous infusion line was used for both ceftriaxone sodium and calcium-containing fluids and in some a precipitate was observed in the intravenous infusion line. At least one fatality has been reported in a neonate in whom ceftriaxone sodium and calcium-containing fluids were administered at different time points via different intravenous lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

<p>For management of a suspected drug overdose, contact your regional Poison Control Centre.</p>
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Ultrasonographic shadows suggesting precipitation in the kidneys accompanied by calcium ceftriaxone precipitate in the urine was observed in one patient dosed with Ceftriaxone Sodium for Injection BP (ceftriaxone sodium) at 10 g/day (2.5 times the maximum recommended dose). No other cases of overdosage has been reported to date with Ceftriaxone Sodium for Injection BP. No specific information on symptoms or treatment is available. Excessive serum concentration of ceftriaxone cannot be reduced by hemodialysis or peritoneal dialysis. Treatment should be symptomatic.

DOSAGE AND ADMINISTRATION

Ceftriaxone Sodium for Injection BP (ceftriaxone sodium) may be administered intravenously or intramuscularly after reconstitution.

Dosage and route of administration should be determined by the severity of infection, susceptibility of the causative organisms, and condition of the patient. The intravenous route is preferable for patients with septicemia or other severe or life-threatening infections.

DOSAGES

Type of infection	Route	Dose	Frequency	Total Daily Dose
Moderate and Severe Infections	I.V. or I.M.	1 or 2 g	q24h	1 or 2 g
		0.5 or 1 g	q12h	1 or 2 g

There is limited experience with daily doses of 3-4 g administered as a single dose or two equally divided doses. The total daily dose should not exceed 4 g.

Uncomplicated Gonorrhoea	I.M.	250 mg	Single dose	—
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Infants and Children (One Month to 12 Years of Age)

Type of infection	Route	Dose	Frequency	Total Daily Dose
Serious Miscellaneous Infections	I.V. or I.M.	25 or 37.5 mg/kg	q12h	50 or 75 mg/kg
The total daily dose should not exceed 2 g. If body weight is 50 kg or more the adult dose should be used.				
Meningitis	I.V. or I.M.	50 mg/kg*	q12h	100 mg/kg

* With or without a loading dose of 75 mg/kg. The total daily dose should not exceed 4 g.

With the exception of gonorrhea, which is treated with a single dose, the administration of Ceftriaxone Sodium for Injection BP should be continued for a minimum of 48 to 72 hours after the patient defervesces or after evidence of bacterial eradication has been obtained, usually 4 to 14 days. In bone and joint infections the average duration of treatment during clinical trials was 6 weeks, with a range of 1 to 13 weeks, depending on the severity of the infection.

When treating infections caused by beta hemolytic streptococcus, it is recommended that therapy be continued for at least 10 days. The average duration of therapy for infections associated with beta hemolytic streptococcus during clinical trials was 2 weeks, with a range of 1 to 5 weeks, depending on the site and severity of the infection.

Prophylaxis (Vaginal or Abdominal Hysterectomy, Coronary Artery Bypass Surgery, Biliary Tract Surgery): For preoperative use as prophylaxis before vaginal or abdominal hysterectomy, coronary artery bypass surgery, or biliary tract surgery in patients at risk of infection, a single dose of 1 g administered 1/2 to 2 hours before surgery is recommended.

Impairment of Renal and/or Hepatic Function: In patients with mild to moderate renal impairment, changes in the dosage regimen are not required, provided liver function is intact. In cases of preterminal renal failure (creatinine clearance less than 10 mL/min), periodic monitoring of serum ceftriaxone concentrations is recommended. The daily dosage should be limited to 2 g or less. In patients with liver damage, there is no need for the dosage to be reduced provided renal function is intact. In cases of coexistent renal and clinically significant hepatic insufficiency, close monitoring of serum ceftriaxone concentrations, at regular intervals, is recommended. If there is evidence of accumulation, dosage should be decreased accordingly.

ADMINISTRATION

Intramuscular: The reconstituted solution of Ceftriaxone Sodium for Injection BP should be administered by deep intragluteal injection. It is recommended that not more than 1 g be injected at a single site. Pain on intramuscular injection is usually mild and less frequent when Ceftriaxone for Injection BP is administered in sterile 1% Lidocaine solution.

Intravenous (bolus) Injection: The reconstituted solution should be administered over approximately 5 minutes. If the distal port of an intravenous administration set is used, stop the primary flow, inject the reconstituted Ceftriaxone Sodium for Injection BP solution and then restart the primary flow. This will prevent mixing with the primary fluid and possible incompatibilities.

Short Intravenous Infusion: The further diluted intravenous solution should be given over a period of 10 to 15 minutes in infants and children and 20 to 30 minutes in adults.

NOTE: Ceftriaxone Sodium for Injection BP solution should not be physically mixed with aminoglycoside antibiotics nor administered at the same site because of possible chemical incompatibility. There have also been literature reports of physical incompatibilities between ceftriaxone and vancomycin, amascrine, or fluconazole.

Do not use diluents containing calcium, such as Ringer’s solution or Hartmann’s solution, to reconstitute Ceftriaxone Sodium for Injection BP vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when Ceftriaxone Sodium for Injection BP is mixed with calcium-containing solutions in the same IV administration line. Ceftriaxone Sodium for Injection BP must not be administered simultaneously with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, Ceftriaxone Sodium for Injection BP and calcium-containing solutions may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid (see **CONTRAINDICATIONS** and **WARNINGS**).

There have been no reports of an interaction between ceftriaxone and oral calcium-containing products or interaction between intramuscular ceftriaxone and calcium-containing products (IV or oral).

SPECIAL HANDLING INSTRUCTIONS

Disposal of syringes/sharps

The following points should be strictly adhered to regarding the use and disposal of syringes and other medicinal sharps:

- Needles and syringes should never be reused.
- Place all used needles and syringes into a sharps container (puncture-proof disposable container).
- Keep this container out of the reach of children.
- Placing used sharps containers in the household waste should be avoided.
- Dispose of the full container according to local requirements or as instructed by your healthcare provider.

Disposal of unused/expired medicines

The release of pharmaceuticals in the environment should be minimized. Medicines should not be disposed of via wastewater, and disposal through household waste should be avoided. Use established "collection systems" if available at your location.

RECONSTITUTION

Tap vial gently to loosen powder prior to reconstitution.

For Intramuscular Use

Reconstitute Ceftriaxone Sodium for Injection BP powder with the appropriate diluent.

- Sterile Water for Injection
- 0.9% Sodium Chloride Injection
- 5% Dextrose Injection
- Bacteriostatic Water for Injection
- 1% Lidocaine Solution

Reconstitute as follows:

Regular Volume Reconstitution Table (I.M.)*				
Vial Size	Volume to be Added to Vial mL	Approximate Available Volume mL	Approximate Average Concentration g/mL	
250 mg	0.9	1.0	0.25	
500 mg	1.8	2.0	0.25	
1.0 g	3.3	4.0	0.25	
2.0 g	6.6	8.0	0.25	

*Shake well until dissolved.

Low Volume Reconstitution Table (I.M.)*			
Vial Size	Volume to be Added to Vial mL	Approximate Available Volume mL	Approximate Average Concentration g/mL
250 mg, 500 mg	Not recommended for this vial size.		
1.0 g	2.2	2.8	0.35
2.0 g	4.4	5.6	0.35

*Shake well until dissolved.

NOTE: SOLUTIONS PREPARED FOR INTRAMUSCULAR USE OR ANY SOLUTION CONTAINING LIDOCAINE OR BACTERIOSTATIC WATER FOR INJECTION SHOULD NEVER BE ADMINISTERED INTRAVENOUSLY.

For Intravenous Use

- Reconstitute only with Sterile Water for Injection.

Reconstitute as follows:

Reconstitution Table (I.V)**			
Vial Size	Volume to be Added to Vial mL	Approximate Available Volume mL	Approximate Average Concentration g/mL
250 mg	2.4	2.5	0.1
500 mg	4.8	5.0	0.1
1.0 g	9.6	10.1	0.1
2.0 g	19.2	20.5	0.1

**Shake well until dissolved. The prepared solution may be further diluted to the desired volume with any of the “Solutions for I.V. Infusion” listed below.

Solutions for I.V. Infusion

- 0.9% Sodium Chloride Injection
- 5% Dextrose Injection
- Dextrose and Sodium Chloride Injection

Pharmacy Bulk Vial Reconstitution for Preparation of Intravenous Infusion Solutions

