

# Ceftriaxone Sandoz

**Ceftriaxone Sodium Ph Eur, powder for injection, 250 mg, 500 mg, 1 g and 2 g (as ceftriaxone)**

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## Presentation

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Ceftriaxone Sandoz is a white to yellowish powder aseptically filled into glass vials.

Ceftriaxone Sandoz 250 mg contains in a 10 ml or 15 ml vial, sterile ceftriaxone sodium equivalent to ceftriaxone 250 mg.

Ceftriaxone Sandoz 500 mg contains in a 10 ml or 15 ml vial, sterile ceftriaxone sodium equivalent to ceftriaxone 500 mg.

Ceftriaxone Sandoz 1 g contains in a 15 ml vial, sterile ceftriaxone sodium equivalent to ceftriaxone 1 g.

Ceftriaxone Sandoz 2 g contains in a 30 ml or 50 ml vial, sterile ceftriaxone sodium equivalent to ceftriaxone 2 g.

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## Uses

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### Actions

#### Pharmacotherapeutic group

J01DA13 – Cephalosporins and related substances, ceftriaxone.

#### Mechanism of action

Beta-lactam antibiotic.

#### Pharmacodynamic effects

Inhibition of bacterial cell wall synthesis.

#### Antibiotic class

Long acting, broad spectrum semi-synthetic cephalosporin for intramuscular or intravenous administration.

#### Antibiotic nature and mode of action

The bactericidal activity of ceftriaxone results from inhibition of bacterial cell wall synthesis. Ceftriaxone exerts *in vitro* activity against a wide range of Gram-negative and Gram-positive micro-organisms. Ceftriaxone is highly stable to most beta-lactamases, both the penicillinases and cephalosporinases, of Gram-positive and Gram-negative bacteria.

#### Susceptibility data

Ceftriaxone is usually active against the following micro-organisms *in vitro* and in clinical infections (refer to [Indications](#)):

##### *Gram-positive aerobes*

*Staphylococcus aureus* (methicillin-sensitive), staphylococci coagulase-negative, *Streptococcus pyogenes* (beta-haemolytic, group A), *Streptococcus agalactiae* (beta-haemolytic, group B), beta-haemolytic streptococci (non-group A or B), *Streptococcus viridans*, *Streptococcus pneumoniae*.

##### *Gram-negative aerobes*

*Acinetobacter lwoffii*, *Acinetobacter anitratus* (mostly *A. baumannii*)\*, *Aeromonas hydrophila*, *Alcaligenes faecalis*, *Alcaligenes odorans*, *Alcaligenes* -like bacteria, *Borrelia burgdorferi*, *Capnocytophaga* spp., *Citrobacter diversus* (including *C. amalonaticus*), *Citrobacter freundii*\*, *Escherichia coli*, *Enterobacter aerogenes*\*, *Enterobacter cloacae*\*, *Enterobacter* spp. (other)\*,

*Haemophilus ducreyi*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Hafnia alvei*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*\*\* , *Moraxella catarrhalis* (former *Branhamella catarrhalis* ), *Moraxella osloensis*, *Moraxella* spp. (other), *Morganella morganii*, *Neisseria gonorrhoea*, *Neisseria meningitidis*, *Pasteurella multocida*, *Plesiomonas shigelloides*, *Proteus mirabilis*, *Proteus penneri* \* , *Proteus vulgaris* \* , *Pseudomonas fluorescens* \* , *Pseudomonas* spp. (other)\*, *Providencia rettgeri* \* , *Providencia* spp. (other), *Salmonella typhi*, *Salmonella* spp. (non-typhoid), *Serratia marcescens* \* , *Serratia* spp. (Other)\*, *Shigella* spp., *Vibrio* spp., *Yersinia enterocolitica*, *Yersinia* spp. (other).

\* Some isolates of these species are resistant to ceftriaxone, mainly due to the production of the chromosomally encoded beta-lactamase.

\*\* Some isolates of these species are resistant due to production of extended spectrum, plasmid-mediated beta-lactamase.

*Note:* many strains of the above micro-organisms that demonstrate multiple resistance to other antibiotics, e.g. amino-penicillins and ureido-penicillins, older cephalosporins and aminoglycosides, are susceptible to ceftriaxone. *Treponema pallidum* is sensitive *in vitro* and in animal experiments. Clinical investigations indicate that primary and secondary syphilis respond well to ceftriaxone therapy.

#### Anaerobic organisms

*Bacteroides* spp. (bile-sensitive)\*, *Clostridium* spp. (excluding *C. difficile* and the *C. perfringens* group), *Fusobacterium nucleatum*, *Fusobacterium* spp. (other), *Gaffkia anaerobica* (formerly *Peptococcus*), *Peptostreptococcus* spp.

\* Some isolates of these species are resistant to ceftriaxone due to beta-lactamase-production.

#### Resistance

Methicillin-resistant *Staphylococcus* spp. are resistant to cephalosporins, including ceftriaxone. In general, *Enterococcus faecalis*, *Enterococcus faecium* and *Listeria monocytogenes* are resistant.

With a few exceptions clinical *P. aeruginosa* isolates are resistant to ceftriaxone.

Many strains of beta-lactamase-producing *Bacteroides* spp. (notably *B. fragilis*) are resistant. *Clostridium difficile* is resistant.

#### Clinically relevant MIC ranges

Susceptibility to ceftriaxone can be determined by the disc diffusion test or by the agar or broth dilution test using standardised techniques for susceptibility testing such as those recommended by the National Committee for Clinical Laboratory Standards (NCCLS). The NCCLS has issued interpretative breakpoints for ceftriaxone from dilution and diffusion techniques. In the dilution test, susceptible organisms were inhibited by a ceftriaxone concentration of 8 mg/l, moderately susceptible organisms were inhibited by ceftriaxone concentrations between 16 to 32 mg/l and resistant organisms were inhibited by a ceftriaxone concentration of 64 mg/l. In the diffusion test using a disc impregnated with ceftriaxone 30 mcg, susceptible organisms were characterised by an inhibition zone diameter of 21 mm, moderately susceptible organisms were characterised by inhibition zone diameters from 20 to 14 mm and resistant organisms were characterised by an inhibition zone diameter of 13 mm. Micro-organisms should be tested with the ceftriaxone disc since it has been shown by *in vitro* tests to be active against certain strains resistant to cephalosporin class discs. Where NCCLS recommendations are not in daily use, alternative, well standardised, susceptibility interpretative guidelines such as those issued by DIN, ICS and others may be substituted.

#### Pharmacokinetics

The pharmacokinetics of ceftriaxone are non-linear and all basic pharmacokinetic parameters, except the elimination half-life, are dose dependent if based on total drug concentrations. An overall mean and the range of means from studies have been presented for the primary pharmacokinetic parameters of ceftriaxone administered in the dose range 0.15 to 3 g.

## **Absorption**

The maximum plasma concentration after a single intramuscular dose of 1 g is about 81 mg/l and is reached in 2 to 3 hours after administration. The area under the plasma concentration-time curve after intramuscular administration is equivalent to that after intravenous administration of an equivalent dose, indicating 100% bioavailability of intramuscularly administered ceftriaxone.

## **Distribution**

The volume of distribution of ceftriaxone is 7 to 12 l. Ceftriaxone exhibits excellent tissue and body fluid penetration after a dose of 1 to 2 g. Ceftriaxone concentrations well above the minimum inhibitory concentrations of most pathogens responsible for infection are detectable for more than 24 hours in over 60 tissues or body fluids including lung, heart, biliary tract/liver, tonsil, middle ear and nasal mucosa, bone as well as cerebrospinal, pleural, prostatic and synovial fluids. Following intravenous administration, ceftriaxone diffuses rapidly into the interstitial fluid, sustaining bactericidal concentrations against susceptible organisms for 24 hours.

### *Protein binding*

Ceftriaxone is reversibly bound to albumin, and the binding decreases with the increase in concentration, e.g. from 95% binding at plasma concentrations less than 100 mg/l to 85% binding at 300 mg/l. Due to the lower albumin content, the proportion of free ceftriaxone in interstitial fluid is correspondingly higher than in plasma.

### *Penetration into particular tissues*

Ceftriaxone penetrates the inflamed meninges of neonates, infants and children: Ceftriaxone concentrations exceed 1.4 mg/l in the Cerebrospinal Fluid (CSF) 24 hours after intravenous injection of ceftriaxone in doses of 50 to 100 mg/kg (neonates and infants respectively). An average peak concentration in CSF of 18 mg/ml is attained about 4 hours after intravenous injection. Mean CSF levels are 17% of plasma concentrations in patients with bacterial meningitis and 4% in patients with aseptic meningitis. In adult meningitis patients, administration of ceftriaxone 50 mg/kg provides within 2 to 24 hours, CSF concentrations several times higher than the minimum inhibitory concentrations required for the most common meningitis pathogens.

Ceftriaxone crosses the placental barrier and is secreted in the breast milk at low concentrations.

## **Metabolism**

Ceftriaxone is not metabolised systemically; but is converted to inactive metabolites by the gut flora.

## **Elimination**

Total plasma clearance is 10 to 22 ml/min. Renal clearance is 5 to 12 ml/min. 50 to 60% of ceftriaxone is excreted unchanged in the urine, while 40 to 50% is excreted unchanged in the bile. The elimination half-life in adults is about 8 hours.

## **Pharmacokinetics in special clinical situations**

### *Neonates and elderly patients*

In neonates, urinary recovery accounts for about 70% of the dose. In infants aged less than 8 days and in elderly persons aged over 75 years the average elimination half-life is usually two to three times that of young adults.

### *Renal or hepatic dysfunction*

In patients with renal or hepatic dysfunction, the pharmacokinetics of ceftriaxone are only minimally altered and the elimination half-life is only slightly increased. If kidney function alone is impaired, biliary elimination of ceftriaxone is increased. Conversely, if liver function alone is impaired, renal elimination is increased.

## **Indications**

Infections caused by pathogens sensitive to ceftriaxone, e.g.: sepsis; meningitis; abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts); infections of the bones, joints, soft

tissue, skin and of wounds; infections in patients with impaired defence mechanisms; renal and urinary tract infections; respiratory tract infections, particularly pneumonia, and ear, nose and throat infections; genital infections, including gonorrhoea.

Perioperative prophylaxis of infections.

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## Dosage and administration

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### Dosage

#### Standard dosage

*Adults and children over 12 years.*

The usual dosage is 1 to 2 g Ceftriaxone Sandoz once daily (every 24 hours). In severe cases or in infections caused by moderately sensitive organisms, the dosage may be raised to 4 g, once daily.

*Neonates, infants and children up to 12 years*

The following dosage schedules are recommended for once daily administration. Neonates (up to 14 days): 20 to 50 mg/kg bodyweight once daily. The daily dose should not exceed 50 mg/kg on account of the immaturity of the infant's enzyme systems. It is not necessary to differentiate between premature and term infants. Infants and children (15 days to 12 years): 20 to 80 mg/kg once daily. For children with bodyweights of 50 kg or more, the usual adult dosage should be used. Intravenous doses of NLT 50 mg/kg bodyweight should be given by infusion over at least 30 minutes.

*Elderly patients*

The dosages recommended for adults require no modification for geriatric patients.

#### Duration of therapy

The duration of therapy varies according to the course of the disease. As with antibiotic therapy in general, administration of Ceftriaxone Sandoz should be continued for a minimum of 48 to 72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.

#### Combination therapy

Synergy between ceftriaxone and aminoglycosides has been demonstrated with many Gram-negative bacteria under experimental conditions. Although enhanced activity of such combinations is not always predictable, it should be considered in severe, life threatening infections due to micro-organisms such as *Pseudomonas aeruginosa*. To avoid an incompatibility reaction, the two medicines must be administered separately at the recommended dosages.

#### Special dosage instructions

*Meningitis*

In bacterial meningitis in infants and children, treatment begins with doses of 100 mg/kg (up to a maximum of 4 g) once daily. As soon as the causative organism has been identified and its sensitivity determined, the dosage can be reduced accordingly. The following duration of therapy has shown to be effective: *Neisseria meningitidis* 4 days; *Haemophilus influenzae* 6 days; *Streptococcus pneumoniae* 7 days.

*Gonorrhoea*

For penicillinase-producing and non-penicillinase-producing strains, give a single intramuscular dose of 250 mg.

*Perioperative prophylaxis*

A single dose of 1 to 2 g depending on the risk of infection given at 30 to 90 minutes prior to surgery. In colorectal surgery, administration of ceftriaxone with or without a 5-nitroimidazole, e.g. ornidazole (separate administration, refer to [Administration](#)) has proven effective.

### *Impaired renal and hepatic function*

In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone provided hepatic function is intact. Only in cases of pre-terminal renal failure (creatinine clearance less than 10 ml/min) should the ceftriaxone dosage not exceed 2 g daily. In patients with liver damage, there is no need to reduce the dosage provided renal function is intact.

In cases of concomitant severe renal and hepatic dysfunction, determine the plasma concentrations of ceftriaxone at regular intervals and if necessary, adjust the dose.

Patients undergoing dialysis require no additional supplementary dosing following the dialysis. Plasma concentrations should, however, be monitored, to determine if dosage adjustments are necessary, since in these patients, the elimination rate may be altered.

### **Administration**

As a general rule, use the solutions immediately after preparation. Reconstituted solutions retain their physical and chemical stability for 24 hours at or below 25°C (or for 48 hours when refrigerated between 2 to 8°C). The solutions range in colour from pale yellow to amber, depending on the concentration and length of storage. The solution colour does not indicate the efficacy or tolerability of the medicine.

Do NOT use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute ceftriaxone. Particulate formation can result.

Ceftriaxone and calcium-containing solutions, including continuous calcium-containing infusions such as parenteral nutrition, should not be mixed or co-administered to any patient irrespective of age, even via different infusion lines at different sites.

Calcium-containing solutions or products must not be administered within 48 hours of the last administration of ceftriaxone.

### **Intramuscular injection**

For intramuscular injection, dissolve Ceftriaxone Sandoz 1 g in 3.5 ml lignocaine hydrochloride or lidocaine hydrochloride solution 1% w/v and inject well within the body of a relatively large muscle. It is recommended not to inject more than 1 g at one site. Never administer the lignocaine or lidocaine solution intravenously.

### **Intravenous injection**

For intravenous injection, dissolve Ceftriaxone Sandoz 250 mg or 500 mg in 5 ml, and Ceftriaxone Sandoz 1 g in 10 ml sterile water for injections. The intravenous administration should be given over 2 to 4 minutes.

### **Intravenous infusion**

The infusion should be given over at least 30 minutes. For intravenous infusion, dissolve Ceftriaxone Sandoz 2 g in 40 ml of one of the following calcium-free infusion solutions: sodium chloride 0.9%, sodium chloride 0.45% + dextrose 2.5%, dextrose 5%, dextrose 10%, dextran 6% in dextrose 5%, hydroxyethyl starch 6 to 10%, water for injections. Ceftriaxone solutions may be incompatible with other medicines or diluents and should not be mixed with or piggybacked into solutions or diluents containing antibiotics or solutes different to those listed above.

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## **Contraindications**

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Ceftriaxone Sandoz is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics. In patients hypersensitive to penicillin, consider the possibility of allergic cross-reactions.

Although the relevant preclinical investigations revealed neither mutagenic nor teratogenic effects, ceftriaxone should not be used in pregnancy (particularly in the first trimester) unless absolutely indicated.

### ***Hyperbilirubinemic neonates***

Ceftriaxone is contraindicated in hyperbilirubinemic neonates, especially premature newborns up to a corrected age of 41 weeks (weeks of gestation + weeks of life) . *In vitro* studies have shown that ceftriaxone can displace bilirubin from its binding to serum albumin and bilirubin encephalopathy can possibly develop in these patients.

### ***Neonates aged 28 days or younger***

Ceftriaxone must not be co-administered with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition, in neonates aged 28 days or younger because of the risk of precipitation of ceftriaxone-calcium salt.

Cases of fatal reactions with ceftriaxone-calcium precipitates in lung and kidneys in neonates have been described. In some cases the infusion lines and the times of administration of ceftriaxone and calcium-containing solutions differed.

Lignocaine should not be used as a diluent for intramuscular injection in patients who are hypersensitive to lignocaine.

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## **Warnings and precautions**

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### ***Warnings***

Ceftriaxone Sandoz should not ordinarily be given to those allergic to cephalosporins or to penicillins, especially where an allergic or urticarial reaction has occurred. As with other cephalosporins, anaphylactic shock cannot be ruled out even if a thorough patient history is taken.

**Pseudomembranous colitis has been reported with nearly all antibacterial agents, including ceftriaxone. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents.****Interactions with calcium-containing products**

There are no reports to date of intravascular or pulmonary precipitations in patients, other than neonates, treated with ceftriaxone and calcium-containing IV solutions. However, the theoretical possibility exists for an interaction between ceftriaxone and IV calcium-containing solutions in patients other than neonates. Therefore, ceftriaxone and calcium-containing solutions, including continuous calcium-containing infusions such as parenteral nutrition, should not be mixed or co-administered to any patient irrespective of age, even via different infusion lines at different sites. However, in patients older than 28 days of age ceftriaxone and calcium containing solutions may be administered sequentially one after another if infusion lines at different sites are used, or if the infusion lines are replaced or thoroughly flushed between infusions with physiological salt solution to avoid precipitation.

In patients requiring continuous infusion with calcium containing TPN solutions, healthcare professionals may wish to consider the use of alternative antibacterial treatments which do not carry a similar risk of precipitation. If use of ceftriaxone is considered necessary in patients requiring continuous nutrition, TPN solutions and ceftriaxone can be administered simultaneously, albeit via different infusion lines at different sites. Alternatively, infusion of TPN solution could be stopped for the period of ceftriaxone infusion, considering the advice to flush infusion lines between solutions. As a further theoretical consideration and based on five half-lives of ceftriaxone, IV calcium-containing solutions and ceftriaxone should not be administered within 48 hours of each other, in any patient.

No data are available on the potential interaction between ceftriaxone and oral calcium-containing products or interaction between IM ceftriaxone and calcium-containing products (IV or oral).

## **Precautions**

Superinfections with non-susceptible micro-organisms may occur as with other antibacterial agents.

Shadows, which have been mistaken for gallstones, have been detected on sonograms of the gallbladder, usually following doses higher than the standard recommended dose. These shadows are, however, precipitates of calcium ceftriaxone that disappear on completion or discontinuation of ceftriaxone therapy. Rarely have these findings been associated with symptoms. In asymptomatic cases discontinuation of treatment is not recommended as the condition is reversible after completion of the treatment. In symptomatic cases, conservative non-surgical management is recommended. Discontinuation of ceftriaxone treatment in symptomatic cases should be at the discretion of the physician.

Cases of pancreatitis, possibly of biliary obstruction aetiology, have been rarely reported in patients treated with ceftriaxone. 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-related biliary precipitation can not be eliminated.

Safety and effectiveness of ceftriaxone in neonates, infants and children have been established for the dosages described under Dosage and administration. *In vitro* studies have shown that ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Ceftriaxone Sandoz should not be used in neonates (especially prematures) at risk of developing bilirubin encephalopathy.

During prolonged treatment, monitor the blood at regular intervals.

## **Pregnancy and lactation**

### **Use in pregnancy**

Assigned Category B1 by the Australian Drug Evaluation Committee. This category includes medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

Studies in animals have not shown evidence of an increased occurrence of foetal damage. Reproductive toxicity studies have been performed in mice and rats at doses up to 20 times the human dose of 2 g/d (586 mg/kg/d in rats), and have not shown evidence of embryotoxicity, foetotoxicity, teratogenicity or adverse effects on male or female fertility, birth or peri- and postnatal development. In primates, no embryotoxicity or teratogenicity was demonstrated at a dose approximately 3 times the human dose (84 mg/kg/d in monkeys). Safety in human pregnancy has not been established. Ceftriaxone crosses the placental barrier.

### **Use in lactation**

Residual ceftriaxone may be present in breast milk at levels corresponding to approximately 0.7 to 4.7% of the maternal dose. Cephalosporins are considered to be compatible with breastfeeding although there are theoretical risks of alterations to infant bowel flora and allergic sensitisation.

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

This medicine is presumed to be safe or unlikely to produce an effect.

## **Other**

### **Preclinical safety data**

Repeated dose administrations in animals revealed the known and reversible side effect of parenterally administered third-generation cephalosporins at high doses (e.g. alteration of laboratory parameters, enteric disturbances and a certain degree of nephrotoxicity). A specific side effect of ceftriaxone is the formation of biliary calculi in the gallbladder of dogs, and to a minor extent, also in monkeys. Ceftriaxone had no effect on reproductive parameters, and was found to have neither mutagenic nor antigenic activity.

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## Adverse effects

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Ceftriaxone is generally well tolerated. During ceftriaxone treatment the following side effects, which were reversible either spontaneously or after withdrawal of the medicine, have been observed.

### Common (1% or more)

Gastrointestinal complaints (about 2% of the cases): loose stools or diarrhoea, nausea, vomiting, stomatitis and glossitis.

Haematological changes (about 2%): eosinophilia, leukopenia, granulocytopenia, haemolytic anaemia, thrombocytopenia. Isolated cases of agranulocytosis (below 500/mm<sup>3</sup>) have been reported, most of them after 10 days of treatment and following total doses of 20 g or more.

### Uncommon (from 0.1% to 1%)

Skin reactions (about 1%): exanthema, allergic dermatitis, pruritus, urticaria, oedema. Isolated cases of severe cutaneous adverse reactions (erythema multiforme, Stevens Johnson syndrome or Lyell's Syndrome/toxic epidermal necrolysis) have been reported.

### Rare (less than 0.1%)

These include headache and dizziness, symptomatic precipitation of ceftriaxone calcium salt in the gallbladder, increase in liver enzymes, oliguria, increase in serum creatinine, genital mycosis, fever, shivering and anaphylactic or anaphylactoid reactions.

In rare cases, phlebitic reactions occurred after intravenous administration. These may be minimised by slow injection over 2 to 4 minutes. Intramuscular injection without lignocaine or lidocaine solution is painful.

Rarely, severe, and in some cases fatal, adverse reactions have been reported in preterm and full-term newborns (aged < 28 days) who had been treated with intravenous ceftriaxone and calcium. Precipitations of ceftriaxone-calcium salt have been observed in lung and kidneys post-mortem.

The high risk of precipitation in newborns is due to their low blood volume and the longer half life of ceftriaxone compared with adults (see Contraindications, Precautions)Pseudomembranous enterocolitis and coagulation disorders have been reported as very rare side effects.

Very rare cases of renal precipitation have been reported, mostly in children older than 3 years and who have been treated with either high daily doses (e.g. NLT 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 or asymptomatic, may lead to renal insufficiency, and is reversible upon discontinuation of ceftriaxone.

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## Interactions

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To date, no impairment of renal function has been observed after concurrent administration of large doses of ceftriaxone and potent diuretics (e.g. furosemide).

There is no evidence that ceftriaxone potentiates the renal toxicity of aminoglycosides.

No effect similar to that of disulfiram has been demonstrated after ingestion of alcohol subsequent to the administration of ceftriaxone. Ceftriaxone does not contain the N-methylthiotetrazole moiety that is associated with possible ethanol intolerance and bleeding problems of certain other cephalosporins.

Probenecid does not modify the elimination of ceftriaxone.

Antagonistic effects have been observed *in vitro* with the combination of chloramphenicol and ceftriaxone.

Precipitation of ceftriaxone-calcium can also occur when ceftriaxone is mixed with calcium-containing solutions in the same IV administration line. Ceftriaxone 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 and calcium-containing solutions may be administered sequentially, one after the other, 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.

Ceftriaxone may adversely affect the efficacy of oral hormonal contraceptives. Consequently, it is advisable to use supplementary (non-hormonal) contraceptive measures during treatment and in the month following treatment.

### ***Influence on diagnostic tests***

A false positive Coomb's test result has been rarely observed in patients treated with ceftriaxone. Ceftriaxone, like other antibiotics, may result in false-positive tests for galactosaemia.

Likewise, non-enzymatic methods for the glucose determination in urine may give false-positive results. Select enzymatic reagents for urinary glucose determination during ceftriaxone therapy.

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## **Overdosage**

In the case of overdose, ceftriaxone concentration would not be reduced by haemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdose should be symptomatic.

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## **Pharmaceutical precautions**

### ***Instructions for use/handling***

Refer to [Dosage and administration](#).

### ***Incompatibilities***

Do not mix Ceftriaxone Sandoz with solutions containing calcium such as Hartmann's solution and Ringer's solution.

According to literature reports, ceftriaxone is incompatible with amsacrine, vancomycin, fluconazole and aminoglycosides.

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

Store the unopened medicine at or below 25°C. Protect from light and moisture. Store the reconstituted medicine below 25°C and use within 24 hours. Alternatively, store the reconstituted medicine between 2 to 8°C and use within 48 hours. Refrigerate, do not freeze.

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## **Medicine classification**

Prescription Medicine.

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## **Package quantities**

Single vial packs. Not all pack sizes and/or strengths may be currently marketed.

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## Further information

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### ***Chemical properties***

Ceftriaxone sodium exists as the disodium salt. The sodium content of ceftriaxone sodium is approximately 83 mg/g (3.6 mEq/g).

### ***Displacement volumes***

#### **250 mg vial**

Ceftriaxone Sandoz 250 mg injection is packaged in a 10 ml or 15 ml vial. Reconstitution with 2 ml diluent results in a final volume of approximately 2.15 ml. Reconstitution with 5 ml diluent results in a final volume of approximately 5.2 ml.

#### **500 mg vial**

Ceftriaxone Sandoz 500 mg injection is packaged in a 10 ml or 15 ml vial. Reconstitution with 2 ml diluent results in a final volume of approximately 2.4 ml. Reconstitution with 5 ml diluent results in a final volume of approximately 5.4 ml.

#### **1 g vial**

Ceftriaxone Sandoz 1 g injection is packaged in a 15 ml vial. Reconstitution with 3.5 ml diluent results in a final volume of approximately 4.2 ml. Reconstitution with 10 ml diluent results in a final volume of approximately 10.8 ml.

#### **2 g vial**

Ceftriaxone Sandoz 2 g injection is packaged in a 30 ml or 50 ml vial. Reconstitution with 19 ml diluent results in a final volume of approximately 20.5 ml. Reconstitution with 40 ml diluent results in a final volume of approximately 41.0 ml. Reconstitution with 50 ml diluent results in a final volume of approximately 51.0 ml.

### ***List of excipients***

Nil.

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## Name and address

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Novartis New Zealand Limited  
Private Bag 65904 Mairangi Bay  
AUCKLAND 0754

Telephone: (09) 361 8100

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## Date of preparation

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18th August 2011