Package leaflet: Information for the patient

Cefazolin 1 g Powder for solution for injection/infusion
Cefazolin 2 g Powder for solution for injection/infusion
Cefazolin (as Cefazolin sodium)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is **Cefazolin 1 g Powder for solution for injection/infusion** and **Cefazolin 2 g Powder for solution for injection/infusion.** In the rest of this leaflet the name of the medicine shall be **Cefazolin.**

What is in this leaflet

1. What Cefazolin is and what it is used for
This medicine contains the active substance cefazolin, which is an antibiotic. Cefazolin is used to treat bacterial infections caused by cefazolin-susceptible bacteria, e.g:
- Infections of skin and soft tissue
- Infections of bones and joints

Cefazolin can also be used before, during and after surgery to prevent possible infections.

2. What you need to know before you are given Cefazolin
Do not use Cefazolin:
- if you are allergic to cefazolin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to any cephalosporin antibiotics.
- have ever had a severe allergic (hypersensitive) reaction to any other type of beta lactam antibiotic (penicillins, monobactams and carbapenems).

Warnings and precautions
Talk to your doctor or pharmacist before using Cefazolin if you:
- Are prone to allergic reactions (e.g. hay fever or bronchial asthma), since then the risk of severe allergic reactions to Cefazolin is increased.
- Have had previously an allergic reaction to other beta-lactam antibiotics (e.g. penicillins), since then there is an increased risk of being allergic to Cefazolin as well.
- Suffer from an impaired kidney or liver function.
- Suffer from disorders of blood clotting (e.g. haemophilia) or your present condition can lead to such defects (parenteral feeding, malnutrition, liver or kidney diseases, reduction in blood platelets which increases risk of bleeding or bruising [thrombocytopenia], administration of medicines that prevent blood clotting [anticoagulants like heparin]).
- Suffer from diseases which can cause bleedings (e.g. gastrointestinal ulcers).
- Suffer from severe persistent diarrhoea during or after treatment with Cefazolin. In this case contact your doctor immediately.

Do not take any anti-diarrhoea medicine without consulting your doctor.
Children
- Cefazolin may not be used in newborn infants and infants below the age of 1 month as the safety of use has not yet been established in this group

Other medicines and Cefazolin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines available without prescription.
Your doctor will take special care if you are using any of the following medicines:
- **Anticoagulants (medicines that prevent blood clotting):** Cefazolin may very rarely lead to disorders of blood clotting. Therefore, if you simultaneously receive cefazolin and medicines that prevent blood clotting (e.g. heparin), a careful and regular control of the coagulation factors is necessary.
- **Probenecid** (medicine for the treatment of joint disease and gout).
- **Medicines potentially harmful to kidney:** Cefazolin may intensify the harmful effect of certain antibiotics (aminoglycosides) and of medicines that cause increase in urination (diuretics, e.g. furosemide) on the kidney. Using Cefazolin and one of these medicines at the same time requires regular monitoring of the kidney function, especially in patients with kidney disease.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Pregnancy
Cefazolin crosses the placenta and can affect the unborn child. Therefore, if you are pregnant, your doctor should only give you cefazolin if clearly necessary and after careful consideration of benefits and risks.
Breast-feeding
Cefazolin passes in small amounts into breast milk. Therefore, breastfeeding should be discontinued during treatment with Cefazolin.
Driving and using machines
Cefazolin has no or negligible influence on the ability to drive and use machines.
Cefazolin contains sodium
1 g vial: This medicine contains 50.6 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.
2 g vial: This medicine contains 101.2 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Cefazolin is given
Administration:
Cefazolin is always administered by healthcare personnel. It will be given as an injection or infusion (into a vein) after being dissolved, or into a muscle (intramuscularly) as a deep IM injection. Your doctor will inform you about the necessary duration and frequency of administration of Cefazolin.
The recommended doses are:
Adult patients with normal kidney function
- Infections caused by bacteria susceptible to this medicine: 1 – 2 g daily, divided into 2 – 3 doses.
- Infections caused by bacteria less susceptible to this medicine: 3 – 4 g daily, divided into 3 – 4 doses.

An increase of the daily dose up to 6 g in three or four equal doses is possible.
Use in children and adolescents
Prematures and infants below the age of one month:
The safety in infants below the age of one month has not been determined.
Children over the age of one month:
- Infections caused by bacteria susceptible to this medicine: 25 – 50 mg / kg body weight / day divided in 2 – 4 single doses, every 6, 8 or 12 hours.
- Infections caused by bacteria less susceptible to this medicine: Up to 100 mg / kg body weight / day divided in 3 – 4 single doses, every 6 – 8 hours.

This product is not recommended for children under 1 month of life.
Elderly patients
No dosage adjustment is required for elderly patients with normal renal function.
Special dosage recommendations
Prevention of infections during surgical procedures
1 g cefazolin 30 - 60 minutes before surgery.
In case of long surgical procedures (2 hours or more), additional 0.5 g - 1 g cefazolin during the operation.
Patients with impaired kidney function
In patients with impairment of the kidney function, the elimination of cefazolin is slower. For this reason, your doctor will adjust the dosage according to the severity of the kidney impairment by reducing the maintenance dose or prolongation of the dosage intervals.
Duration of treatment
The treatment duration depends on the severity of the infection as well as on your recovery from your illness.
If you are given more Cefazolin than you should
Since the medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much.
Symptoms of overdose are headache, dizziness (vertigo), sensation of pricking or tingling on the skin (paraesthesia), restlessness (agitation), involuntary twitching of a muscle or a group of muscles (myoclonia) and cramps (convulsions). If these symptoms occur talk to your doctor immediately.
In emergencies, your physician must take the necessary measures for the treatment of symptoms of overdose.
If you miss a dose of Cefazolin
A double dose must not be given to make up for a forgotten dose. A forgotten dose should only be given before the next regular dose if the time until the next regular dose is long enough.
If the treatment with Cefazolin is interrupted or discontinued too early
Low dosage, irregular administration or stopping the treatment too early can compromise the outcome of the therapy or lead to a relapse, that is more difficult to treat. Please follow the instructions of your doctor.

The following information is intended for healthcare professionals only:

Preparation and handling
Preparation of the solution
For each route of administration see the table for addition volumes and solution concentrations, which may be useful when fractional doses are required.
Guidelines for adult dosage
Intramuscular injection
Cefazolin 1 g:
Reconstitute Cefazolin with one of the following compatible diluents according to the dilution table that follows:
- water for injection
- 10% glucose solution
- 0.9% sodium chloride solution
- 0.5% lidocaine HCl solution

Shake well until contents of the vial are fully dissolved and inject as deep IM injection.

Reconstitution table for intramuscular injection

Content per vial	Amount of diluent to be added	Approximate concentration
1 g	2.5 mL	330 mg / mL

For the amount of diluent to be added for paediatric population please refer to section Guidelines for paediatric dosage.
Use of lidocaine:
In case a lidocaine solution is used as a solvent, cefazolin solutions must only be used for intramuscular injection.
Contraindications to lidocaine, warnings and other relevant information as detailed in the Summary of Product Characteristics of lidocaine must be considered before use.
The lidocaine solution should never be administered intravenously.
IM injection with lidocaine as solvent is indicated for children over 30 months old.
Cefazolin 2 g: Should not be used for intramuscular administration.
Intravenous injection
Reconstitute Cefazolin with of one of the following compatible diluents according to the dilution table that follows:
- water for injections
- 0.9% sodium chloride solution
- 5% glucose solution
- 10% glucose solution

Reconstitution table for intravenous injection

Content per vial	Minimum amount of diluent to be added	Approximate concentration
1 g	4 mL	220 mg / mL

Cefazolin is to be injected slowly over three to five minutes. In no case should the solution be injected in less than 3 minutes. This should be done directly into the vein or into the tube from which the patient receives intravenous solution.
Single doses exceeding 1 g should be given as intravenous infusion over 30 to 60 minutes.
Guidelines for paediatric dosage:
1 g vial: The content of 1 vial (1000 mg cefazolin) is dissolved in 4 mL of a compatible solvent (i.e. concentration approx. 220 mg / mL). The respective volume of this solution to be used is indicated in table 1 in addition to the dose in mg.
2 g vial: The content of 1 vial (2000 mg cefazolin) is dissolved in 10 ml of a compatible solvent (i.e. concentration approx. 180 mg / mL). The respective volume of this solution to be used is indicated in table 2 in addition to the dose in mg.
For the amount of diluent to be added for paediatric population please refer to section Guidelines for paediatric dosage. For volumes inferior of 1 mL, please use a 0.5 mL syringe for better accuracy of dosing.
Intravenous infusion
Cefazolin should first be reconstituted with one of the diluents detailed as compatible for intravenous injection.
Further dilution should take place with one of the following compatible diluents according to the dilution table that follows:
- sodium chloride 0.9% solution
- glucose 5%
- Ringer's solution
- lactated Ringer's solution
- water for injections

Dilution table for intravenous infusion

Content per vial	Reconstitution	Dilution	Approximate concentration
	Minimum amount of diluent to be added	Amount of diluent to be added	
1 g	4 mL	50 mL - 100 mL	20 mg / mL - 10 mg / mL
2 g	8 mL	50 mL - 100 mL	40 mg / mL - 20 mg / mL

For Cefazolin 2 g, if smaller doses are needed, it is recommended to use half of the reconstituted solution (about 4 mL with 1 g cefazolin; i.e. half of the vial content) and to add a compatible diluent to a final volume of 100 mL (resulting concentration about 10 mg / mL). The required amount of this diluted solution can then be administered to the patient over the prescribed time.Cefazolin solutions containing lidocaine should never be administered intravenously. As for all parenteral medicinal products, inspect the reconstituted solution visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and practically free from particles. The reconstituted product is for single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Incompatibilities
Cefazolin is incompatible with amikacin disulfate, amobarbital-sodium, ascorbic acid, bleomycin sulphate, calcium gluceptate, calcium gluconate, cimetidine hydrochloride, colistin methat-sodium, erythromycin gluceptate, kanamycin sulphate, oxytetracyclin hydrochloride, pentobarbital-sodium, polymyxin-B-sulphate and tetracycline hydrochloride.
Posology and method of administration
The dosage as well as the method of administration are dependent on the location and severity of the infection and on the clinical and bacteriological progress. Local therapeutic guidance should be taken into consideration.
Adults and adolescents (above 12 years of age and ≥ 40 kg bodyweight)
- Infections caused by sensitive micro-organisms: 1 g – 2 g cefazolin per day divided into 2 – 3 equal doses.
- Infections caused by moderately sensitive micro-organisms: 3 g – 4 g cefazolin per day divided into 3 – 4 equal doses.

In severe infections, doses of up to 6 g per day can be administered in three or four equal doses (one dose every 6 or 8 hours).
Special dosage recommendations
Peri-operative prophylaxis
- To prevent postoperative infection in contaminated or potentially contaminated surgery, recommended doses are: 1 g cefazolin 30 – 60 minutes before surgery
- In case of long surgical interventions (2 hours or more) additional 0.5 – 1 g cefazolin during the intervention.
- Prolonged continuation of administration beyond the surgical intervention should be supported by national official guidance.

It is important that (1) the preoperative dose be given just (30 min to 1 hour) prior to the start of surgery so that adequate antibiotic levels are present in the serum and tissues at the time of initial surgical incision; and (2) cefazolin be administered, if necessary, at appropriate intervals during surgery to provide sufficient levels of the antibiotic at the anticipated moments of greatest exposure to infective organisms.
Adult patients with renal impairment
Adults with renal impairment may need a lower dose to avoid overlapping.
This lower dose may be guided by determining blood levels. If not possible, the dosage can be established based on creatinine clearance.

Cefazolin maintenance therapy in patients with renal impairment

Creatinine clearance (ml/min)	Serum creatinine (mg/dl)	Dosage
≥ 55	≤ 1.5	Normal dose and normal dosage interval
35 - 54	1.6 - 3.0	Normal dose, every 8 hours
11 - 34	3.1 - 4.5	Half of the normal dose every 12 hours
≤ 10	≥ 4.6	Half of the normal dose every 18-24 hours

In haemodialysis patients, the treatment schedule depends on the dialysis conditions.

Guidelines for adult dosage
Reconstitution table for intramuscular injection

Content per vial	Amount of diluent to be added	Approximate concentration
1 g	2.5 mL	330 mg / mL

Reconstitution table for intravenous injection

Content per vial	Minimum amount of diluent to be added	Approximate concentration
1 g	4 mL	220 mg / mL

Paediatric population:
Infections caused by sensitive microorganisms
A dose of 25 – 50 mg / kg body weight divided into two to four equal doses per day is recommended (one dose every 6, 8 or 12 hours).
Infections caused by moderately sensitive microorganisms
A dose of up to 100 mg / kg body weight divided in three or four equal doses is recommended (one dose every 6 or 8 hours).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must stop taking the medicine and speak to your doctor straight away if you notice any of these symptoms:
Uncommon: may affect up to 1 in 100 people
- redness of the skin (erythema), widespread skin rash (erythema multiforme or exanthema), hives (red, itchy, bumpy skin rash) on the surface of the skin (urticaria), fever, swelling beneath the skin (angioedema) and/or swelling of the lung tissue possibly with a cough and breathing difficulties (interstitial pneumonia or pneumonitis), as these side effects may indicate an allergic reaction to this medicine.

Rare: may affect up to 1 in 1000 people
- jaundice (yellow colour in the skin and whites of the eyes).
- severe skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome) or a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

Very rare: may affect up to 1 in 10,000 people
- a severe allergic reaction (anaphylactic shock) with breathing difficulty, swelling of the throat, face, eyelids or lips, increased heart rate and falling blood pressure. This reaction may start soon after you first take the medicine, or it might start later.

The following side effect has been reported but its frequency of occurrence is unknown:
- severe and frequent diarrhoea, sometimes containing blood, as this may indicate a more serious condition (pseudomembranous colitis).

The following side effects may also occur during the use of cefazolin containing products:
Common: may affect up to 1 in 10 people
- mild gastrointestinal disturbances (loss of appetite, diarrhoea, nausea, vomiting, severe and frequent diarrhoea). These side effects usually resolve after a few days.
- injection into the muscle may cause pain at the location of the injection which may sometimes include hardening of the skin and soft tissue at the same site.

Uncommon: may affect up to 1 in 100 people
- oral thrush (thick white or cream-coloured deposits in the mouth and tongue).
- fits/convulsions in patients with kidney problems.
- swelling of a vein caused by a blood clot forming following injection into the muscle (thrombophlebitis).

Rare: may affect up to 1 in 1000 people
- bacterial infection of male or female genitals with symptoms such as itching, redness, swelling and female discharge (genital candidiasis, monoliasis, vaginitis).
- increase or decrease in blood glucose concentration (hyperglycaemia or hypoglycaemia).
- reversible blood abnormalities including the reduction or increase in the number of red and white blood cells (leukopenia, granulocytopenia, neutropenia, thrombocytopenia, leukocytosis, granulocytosis, monocytosis, lymphocytopenia, basophilia and eosinophilia) which may cause bleeding, easy bruising and/or skin discolouration (confirmed by blood test).
- feelings of dizziness, tiredness and a general feeling of being unwell.
- chest pain, excess fluid in the lungs, shortness of breath, cough, stuffy nose (rhinitis).
- liver problems (such as transient elevation of alkaline phosphatase or transient hepatitis) with symptoms such as an increase in liver enzymes (alanine transaminase (ALT), aspartate transaminase (AST), gamma glutamyl transpeptidase (gamma GT) and lactate dehydrogenase (LDH)) and bilirubin (a product of the breakdown of blood cells) in bile or urine (diagnosed by blood test).
- kidney problems (nephrotoxicity, interstitial nephritis, undefined nephropathy, proteinuria) with symptoms such as kidney swelling and an increase of nitrogen in the body that may be diagnosed by urine tests, usually only occurring in patients taking cefazolin at the same time as other medicines that can cause kidney problems.

Very rare: may affect up to 1 in 10,000 people
- itching of the anus or genitalia (pruritus).
- blood not clotting properly which may result in increased bleeding. This may be resolved by increasing vitamin K intake and should be confirmed by blood test (see section 2).
- sleep disorders including nightmares and being unable to sleep (insomnia).
- feelings of nervousness or anxiety, drowsiness, weakness, hot flushes, disturbed colour vision, vertigo and epileptic seizures (involuntary rapid and repeated muscle contraction and relaxation).

Not known: frequency cannot be estimated from the available data
- long-term or repeated treatment with cefazolin may lead to further infection by cefazolin resistant fungi or bacteria (superinfection).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Cefazolin
Keep this medicine out of the sight and reach of children.
Do not use Cefazolin after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.
Store below 30°C. Keep the vials in the outer carton in order to protect from light.
After reconstitution/dilution
Chemical and physical stability has been demonstrated for 12 hours at 25°C and for up to 24 hours at 2 – 8°C.
From a microbiological point of view, unless the method of opening/ reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than the times stated above for the chemical and physical in-use stability.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Cefazolin contains
- The active substance is cefazolin.
  1 g vial: Each vial contains 1 g cefazolin (as cefazolin sodium).
  2 g vial: Each vial contains 2 g cefazolin (as cefazolin sodium).

What Cefazolin looks like and contents of the pack
Cefazolin is a white or almost white powder for solution for injection/infusion. The product is available in glass vials in packs of 1, 10 and 50 vials. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
Marketing Authorisation Holder:
Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer responsible for batch release:
DEMO S.A. PHARMACEUTICAL INDUSTRY,
21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece,
T: +30 210 8161802, **F:** +30 2108161587.
This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom:	Cefazolin 1 g Powder for solution for injection/infusion Cefazolin 2 g Powder for solution for injection/infusion
Cyprus:	Cefazolin/Noridem 1 g Κόνις για ενέσιμο διάλυμα/διάλυμα προς έγχυση Cefazolin/ Noridem 2 g Κόνις για ενέσιμο διάλυμα/ διάλυμα προς έγχυση
Germany:	Cefazolin Noridem 1 g Pulver zur Herstellung einer Injektions-/ Infusionslösung Cefazolin Noridem 2 g Pulver zur Herstellung einer Injektions-/ Infusionslösung
France:	CEFAZOLINE NORIDEM 1 g poudre pour solution injectable/pour perfusion CEFAZOLINE NORIDEM 2 g poudre pour solution injectable/pour perfusion
Belgium:	Cefazoline Noridem 1 g poudre pour solution injectable/pour perfusion - poeder voor oplossing voor injectie/infusie - Pulver zur Herstellung einer Injektions-/ Infusionslösung Cefazoline Noridem 2 g poudre pour solution injectable/pour perfusion - poeder voor oplossing voor injectie/ infusie - Pulver zur Herstellung einer Injektions-/ Infusionslösung
Poland:	Cefazolin Noridem
Slovakia:	Cefazolin Noridem 1 g prášok na injekčný/infúzny roztok Cefazolin Noridem 2 g prášok na injekčný /infúzny roztok
Czech Republic:	Cefazolin Noridem

This leaflet was last revised in 12/2018.

If this leaflet is difficult to see or read please contact the following address for help: Athlone Laboratories, Ballymurray, Co. Roscommon, Ireland, Tel +353-9066-61109, Email medical@athlone-laboratories.com.

Prematures and infants below the age of 1 month
Since safety of use in prematures and infants below the age of one month has not been determined, the use of Cefazolin in these patients is not recommended.
Guidelines for paediatric dosage
Intravenous injection
1 g vial: The content of 1 vial (1000 mg cefazolin) is dissolved in 4 mL of a compatible solvent (i.e. concentration approx. 220 mg / mL). The respective volume of this solution to be used is indicated in table 1 in addition to the dose in mg.
2 g vial: The content of 1 vial (2000 mg cefazolin) is dissolved in 10 mL of a compatible solvent (i.e. concentration approx. 180 mg / mL). The respective volume of this solution to be used is indicated in table 2 in addition to the dose in mg.
Intravenous administration of lidocaine solutions must be strictly avoided.

Table 1: Appropriate volumes for intravenous and intramuscular injection for paediatric patients for Cefazolin 1 g Powder for solution for injection/infusion

Body weight	Strength	5 kg	10 kg	15 kg	20 kg	25 kg
Divided dose every 12 hours at 25 mg / kg body weight / day	1-g vial	63 mg;	125 mg;	188 mg;	250 mg;	313 mg;
		0.29 mL	0.57 mL	0.85 mL	1.14 mL	1.42 mL
Divided dose every 8 hours at 25 mg / kg body weight / day	1-g vial	42 mg;	85 mg;	125 mg;	167 mg;	208 mg;
		0.19 mL	0.439 mL	0.57 mL	0.76 mL	0.94 mL
Divided dose every 6 hours at 25 mg / kg body weight / day	1-g vial	31 mg;	62 mg;	94 mg;	125 mg;	156 mg;
		0.14 mL	0.28 mL	0.43 mL	0.57 mL	0.71 mL
Divided dose every 12 hours at 50 mg / kg body weight / day	1-g vial	125 mg	250 mg;	375 mg;	500 mg;	625 mg;
		0.57 mL	1.14 mL	1.7 mL	2.27 mL*	2.84 mL*
Divided dose every 8 hours at 50 mg / kg body weight/ day	1-g vial	83 mg;	166 mg;	250 mg;	333 mg;	417 mg;
		0.438 mL	0.75 mL	1.14 mL	1.51 mL	1.89 mL
Divided dose every 6 hours at 50 mg / kg body weight/ day	1-g vial	63 mg;	125 mg;	188 mg;	250 mg;	313 mg;
		0.29 mL	0.57 mL	0.85 mL	1.14 mL	1.42 mL
Divided dose every 8 hours at 100 mg / kg body weight/ day	1-g vial	167 mg;	333 mg;	500 mg;	667 mg;	833 mg;
		0.76 mL	1.51 mL	2.27 mL*	3.03 mL*	3.79 mL*
Divided dose every 6 hours at 100 mg / kg body weight/ day	1-g vial	125 mg	250 mg;	375 mg;	500 mg;	625 mg;
		0.57 mL	1.14 mL	1.7 mL	2.27 mL*	2.84 mL*
Divided dose every 12 hours at 50 mg / kg body weight / day	2-g vial	125 mg	250 mg;	375 mg;	500 mg;	625 mg;
		0.69 mL	1.39 mL	2.08 mL	2.78 mL	3.47 mL
Divided dose every 8 hours at 50 mg / kg body weight/ day	2-g vial	83 mg;	166 mg;	250 mg;	333 mg;	417 mg;
		0.46 mL	0.92 mL	1.39 mL	1.85 mL	2.32 mL
Divided dose every 6 hours at 50 mg / kg body weight/ day	2-g vial	63 mg;	125 mg;	188 mg;	250 mg;	313 mg;
		0.35 mL	0.69 mL	1.04 mL	1.39 mL	1.74 mL
Divided dose every 8 hours at 100 mg / kg body weight/ day	2-g vial	167 mg;	333 mg;	500 mg;	667 mg;	833 mg;
		0.93 mL	1.85 mL	2.78 mL	3.7 mL	4.63 mL
Divided dose every 6 hours at 100 mg / kg body weight/ day	2-g vial	125 mg	250 mg;	375 mg;	500 mg;	625 mg;
		0.69 mL	1.39 mL	2.08 mL	2.78 mL	3.47 mL*

* For intramuscular administration, when the calculated volume of each individual administration exceeds 2 mL, it is preferable to select a dosage scheme with more divided doses throughout the day (3 or 4) or divide the volume to be administered into equal parts between two different injection sites

Table 2: Appropriate volumes for intravenous injection for paediatric patients for Cefazolin 2 g Powder for solution for injection/infusion

Body weight	Strength	5 kg	10 kg	15 kg	20 kg	25 kg
Divided dose every 12 hours at 25 mg / kg body weight/ day	2-g vial	63 mg;	125 mg;	188 mg;	250 mg;	313 mg;
		0.35 mL	0.69 mL	1.04 mL	1.39 mL	1.74 mL
Divided dose every 8 hours at 25 mg / kg body weight/ day	2-g vial	42 mg;	85 mg;	125 mg;	167 mg;	208 mg;
		0.23 mL	0.47mL	0.69 mL	0.93 mL	1.15 mL
Divided dose every 6 hours at 25 mg / kg body weight/ day	2-g vial	31 mg;	62 mg;	94 mg;	125 mg;	156 mg;
		0.17 mL	0.34 mL	0.52 mL	0.69 mL	0.87 mL

For volumes inferior of 1 mL, please use a 0.5 mL syringe for better accuracy of dosing.
Intramuscular injection
The content of 1 vial (1000 mg cefazolin) is dissolved in 4 mL of a compatible solvent (i.e. concentration approx. 220 mg / mL) and appropriate volume (as indicated in table 1) is withdrawn from the reconstituted solution and administered by intramuscular injection. For administration in children younger than 30 months of age, cefazolin should not be dissolved in lidocaine solution.
Intravenous infusion
The dosage can be given as intravenous infusion, using the reconstituted and further diluted solution (10 mg / mL) described in subsection "*Intravenous infusion*" of the **Guidelines for adult dosage.**
Paediatric patients with renal impairment
Children with renal impairment (like adults) may need a lower dose to avoid overlapping. This lower dose may be guided by determining blood levels. If not possible, the dosage may be determined based on creatinine clearance, according to the following guidelines. In children with moderate impairment (creatinine clearance 40 – 20 mL / min), 25 % of the normal daily dose, divided into doses every 12 hours are sufficient. In children with severe impairment (creatinine 20 – 5 mL / min) will be 10 % of normal daily dose, given every 24 hours are sufficient. All these guidelines are valid after an initial starting dose.
Elderly patients:
In elderly patients with normal renal function no dosage adjustment is necessary.
Method of administration
Cefazolin 1 g may be administered as a deep IM injection or by slow intravenous injection or intravenous infusion after dilution.
Cefazolin 2 g may be administered by slow intravenous injection or intravenous infusion after dilution. Single doses exceeding 1 g should be given as intravenous infusion.
The volume and type of diluent to be used for the reconstitution is dependent upon the method of administration.
For instructions on the reconstitution of the medicinal product before administration, please see section Preparation and handling. If lidocaine is used as a solvent, the resulting solution should never be administered intravenously. The information in the Summary of Product Characteristics of lidocaine should be considered.
Duration of treatment
The duration of the treatment depends on the severity of the infection as well as on the clinical and bacteriological progress.
Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Overdose
Symptoms of an overdose are headache, vertigo, paraesthesia, central nervous disorders such as agitation, myoclonia and convulsions. In case of poisoning, elimination accelerating measures are indicated. A specific antidote does not exist. Cefazolin can be haemodialysed.