Package leaflet: Information for the patient

Cefazolin 2 g powder for solution for injection/infusion

cefazolin (as cefazolin sodium)

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- 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 2 g Powder for solution for injection/infusion but is referred to as Cefazolin throughout the rest of this leaflet.

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-sensitive bacteria, such as:
- Infections of the skin and soft tissue.
- Infections of the 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

Cefazolin must not be given
- if you are allergic to cefazolin.
- if you have ever had a severe allergic reaction to penicillin or a similar antibiotic.
- if you are allergic to lidocaine and you are to be given Cefazolin as an injection into a muscle

Warnings and precautions
Talk to your doctor or pharmacist before you are given Cefazolin:
- if you have ever had a mild allergic reaction (such as skin rashes that may be itchy) to penicillin or similar antibiotics.
- if you have any allergies not mentioned in this leaflet.
- if you have ever had intestinal problems, especially colitis (inflammation of the bowel).
- if you have kidney problems.
- if you are on a low-sodium diet.

Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with cefazolin. Stop immediately cefazolin and contact immediately your doctor or medical emergencies if you notice any of these signs.

Risk factors that lead to vitamin K deficiency or risk factors that affect other blood clotting mechanisms.

In rare cases, blood clotting disorders can occur during treatment with cefazolin. In addition, blood clotting changes are possible in patients with diseases that can cause or worsen bleeding, such as haemophilia, stomach or bowel ulcers. In these cases, your blood clotting will be monitored.

This medicine must not be injected in the area around the spinal cord (intrathecally) as there have been reports of central nervous system toxicity (including seizures).

Long-term treatment with Cefazolin may cause secondary infections. Your doctor will monitor you closely for their development and provide treatment if necessary.

Children
Cefazolin should not be given to premature babies and infants in the first month of life.

Other medicines and Cefazolin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This includes non-prescription medicines and herbal medicines, because Cefazolin can affect the way some medicines work. Also, some medicines can affect how Cefazolin works.

It is very important to talk to your doctor or nurse, especially if you are taking any of the following medicines:
- aminoglycosides or other antibiotics (used to treat infections)
- probenecid (used to treat gout)
- vitamin K
- anticoagulants (blood thinning medicines)
- furosemide (diuretics)

You should also tell your doctor or nurse if you have tests to measure levels of glucose or other blood tests.

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 nurse for advice before you are given this medicine.

Driving and using machines
Cefazolin has no influence on the ability to drive and use machines. However, side effects may occur which may affect the ability to drive and use machines (see also section 4, Possible side effects).

Cefazolin contains sodium
This medicine contains approximately 101.2 mg of sodium (table salt) in each vial. This is equivalent to 5.1% of the recommended maximum daily dietary intake of sodium for an adult.
This must be taken into consideration by patients on a controlled sodium diet.

3. How Cefazolin is given

Administration
Cefazolin is always administered by a healthcare professional. It will be given as an injection or infusion (into a vein) after being dissolved.

Your doctor will inform you about the necessary duration and frequency of administration of Cefazolin.

The recommended doses are:

Adults 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

Premature babies 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 age.

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 kidney problems
If you have problems with your kidneys, you may be given a lower dose or increase the time between each dose.

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
If you think you have missed a dose of Cefazolin, contact your doctor or nurse immediately.
A double dose must not be given to make up for a forgotten dose.

If treatment with Cefazolin is interrupted or stopped 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..

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

4. Possible side effects

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

Severe allergic reactions (very rare, may affect up to 1 in 10 000 people)
If you have a severe allergic reaction, tell a doctor immediately.
Possible signs can be:
- Sudden swelling of the face, throat, lips or mouth, which may cause difficulty breathing or swallowing,
- Sudden swelling of the hands, feet and ankles.

Other possible side effects

Common (may affect up to 1 in 10 people):
- skin rash,
- nausea and vomiting,
- diarrhoea,
- pain or skin hardening at the injection site.

Uncommon (may affect up to 1 in 100 people):
- yeast infection in the mouth,
- fever,
- seizures (fits),
- inflammation of the veins,
- skin redness and itching, joint pain, skin lesions, widespread rash and hives.

Rare (may affect up to 1 in 1,000 people):
- genital infection, vaginal thrush – sore and itchy vagina or vaginal discharge,
- prolonged use can lead to overgrowth of non-susceptible bacteria,
- increase or decrease in the number of blood cells,
- hypergylcaemia (high blood sugar),
- hypoglycaemia (low blood sugar),
- dizziness
- respiratory (breathing) disorders,
- kidney and urinary disorders,
- cough,
- runny nose,
- loss of appetite,
- liver impairment (detectable with blood analysis), jaundice,
- rapidly evolving severe rash (with blisters on the skin and skin peeling, and possible blisters in the mouth),
- severe fatigue and weakness,
- chest pain.

Very rare (may affect up to 1 in 10,000 people):
- blood clotting disorders,
- inflammation of the colon. Symptoms include diarrhoea (usually with blood and mucus), abdominal pain and fever,
- genital itching.

Not known (frequency cannot be estimated from the available data):
Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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.
This medicinal product does not require any special temperature storage conditions.
Keep the vials in the outer carton in order to protect from light.

For storage conditions after reconstitution and dilution of the medicinal product, see the end of the package leaflet under "The following information is intended for healthcare professionals".

Do not use this medicine after the expiry date which is stated on the vial label and box after "EXP". The expiry date refers to the last day of that month.

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 (as cefazolin sodium).
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. It is available in glass vials in packs of 1 and 10 vials.
Not all pack sizes may be marketed.

Marketing authorisation holder:
ACS Dobfar S.p.A.
Viale Addetta 4/12
20067 Tribiano (MI)
Italy

Manufacturer:
ACS Dobfar S.p.A.
Via A. Fleming, 2
37135 Verona
Italy

This leaflet was last revised in April 2026.

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 2 g powder for solution for injection/infusion should not be used for intramuscular administration.

Intravenous injection

Reconstitute Cefazolin with one of the following compatible diluents according to the dilution table that follows:

- water for injections
- 9 mg/mL (0.9%) sodium chloride solution or
- 50 mg/mL (5%) glucose solution
- 100 mg/ml (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. Injection 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:
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 1 in addition to the dose in mg. For the amount of diluent to be added for the paediatric population, please refer to section Guidelines for paediatric dosage. For volumes less than 1 mL, please use a 0.5 ml syringe for better accuracy of dosing.

Intravenous infusion
Cefazolin should first be reconstituted with water for injection and diluted with one of the following compatible diluents according to the dilution table that follows:

- 9 mg/mL (0.9%) sodium chloride solution
- 50 mg/mL (5%) glucose solution

Dilution table **for intravenous infusion**

Content per vial	Reconstitution	Dilution	Diluent	Theoretical concentration
	Minimum amount of water for injection to be added	Final volume of solution		
2 g	5 ml	50 ml	0,9 % sodium chloride or 5 % glucose	40 mg/ml
2 g	5 ml	100 ml	0,9 % sodium chloride	20 mg/ml

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, oxytetracycline 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 microorganisms:
  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/100 ml)**	**Dosage**

≥ 55	≤ 1.5	Normal dose and normal dosing 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 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).

Premature babies and infants below the age of 1 month
Since safety of use in premature babies 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
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 1 in addition to the dose in mg.

Table 1: Appropriate volumes for intravenous injection for paediatric patients for Cefazolin 2 g powder for solution for injection/infusion

Body weight in kg	**5 kg**	**10 kg**	**15 kg**	**20 kg**	**25 kg**
25 mg/kg/day: dose every 12 hours	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
25 mg/kg/day: dose every 8 hours	42 mg	85 mg	125 mg	167 mg	208 mg
	0.23 ml	0.47 ml	0.69 ml	0.93 ml	1.15 ml
25 mg/kg/day: dose every 6 hours	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
50 mg/kg/day: dose every 12 hours	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

50 mg/kg/day: dose every 8 hours	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
50 mg/kg/day: dose every 6 hours	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
100 mg/kg/day: dose every 8 hours	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
100 mg/kg/day: dose every 6 hours	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 volumes less than 1 ml, please use a 0.5 ml syringe for better dosing accuracy.

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
No dose adjustment is required in elderly patients with normal renal function.

Method of administration
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.

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 overdose

An overdose can cause pain, inflammatory reactions and phlebitis at the injection site. Parenteral administration of high doses of cephalosporins can cause dizziness, paraesthesia and headache. Following overdose with cephalosporins, convulsions may occur especially in patients with renal disease.

Following an overdose, the following abnormal laboratory values may occur: increase in creatinine levels, BUN, liver enzymes and bilirubin, a positive Coombs' test, thrombocythaemia and thrombocytopenia, eosinophilia, leukopenia and prolongation of prothrombin time.

Treatment of overdose
If convulsions occur, administration of the drug should be discontinued immediately. Treatment with antiepileptics may be indicated. Vital body functions and parameters should be monitored closely. In case of a severe overdose where the patient is no longer responsive to other treatments, haemodialysis with haemoperfusion may be effective, although this has not been proven.

Shelf life

After reconstitution for intravenous injection
The reconstituted solution should be administered immediately after preparation.

After reconstitution and dilution for infusion
Chemical and physical stability of the diluted product in 9 mg/ml (0.9%) sodium chloride solution at concentrations 20 mg/ml and 40 mg/ml and in 50 mg/ml (5%) glucose solution at concentrations 40 mg/ml has been demonstrated for 4 hours at 25 ± 2 °C and 3 days at 5 ± 3°C.

From a microbiological point of view, 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 24 hours at 5 ± 3 °C, unless reconstitution has taken place in controlled and validated aseptic conditions.
Store protected from light.