PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr] CEFAZOLIN INJECTION, USP

20 mg / mL cefazolin (as cefazolin sodium) in single-dose GALAXY containers

Ready-to-Use

Sterile Solution

Antibiotic

Baxter Corporation
7125 Mississauga Road
Mississauga, Ontario
L5N 0C2

Date of Preparation:
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Control No: 215094

PRODUCT MONOGRAPH

Pr CEFAZOLIN INJECTION, USP

THERAPEUTIC CLASSIFICATION

Antibiotic

ACTION AND CLINICAL PHARMACOLOGY

Cefazolin is a cephalosporin antibiotic for parenteral administration. Cefazolin exerts its bactericidal effect by inhibiting bacterial cell wall synthesis. Cefazolin is about 85% bound to serum protein. The peak level in serum is approximately 32-42 mg/mL after an intramuscular (i.m.) injection of 500 mg. Over 80% of injected cefazolin is excreted in the urine during the first 24 hours after i.m. injection; most is excreted during the first 4-6 hours.

INDICATIONS AND CLINICAL USE

CEFAZOLIN INJECTION, USP is indicated in the treatment of the following infections when caused by susceptible strains of the listed organisms:

RESPIRATORY TRACT INFECTIONS caused by *Streptococcus pneumoniae, Klebsiella pneumoniae, Hemophilus influenzae, Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant) and group A *beta-haemolytic streptococci*.

URINARY TRACT INFECTIONS caused by *Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae* and some strains of enterobacter, and enterococci. See NOTE below.

SKIN AND SOFT TISSUE INFECTIONS caused by *Staphylococcus aureus* (penicillin- sensitive and penicillin- resistant), group A beta-haemolytic streptococci and other strains of streptococci.

BONE AND JOINT INFECTIONS caused by *Staphylococcus aureus.*

SEPTICEMIA caused by *Streptococcus pneumoniae, Staphylococcus aureus* (penicillin-sensitive and penicillin resistant), *Proteus mirabilis, Escherichia coli* and *Klebsiella pneumoniae*. See NOTE below.

ENDOCARDITIS caused by *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant) and group A *beta haemolytic streptococci.*

Determine susceptibility of the causative organism to cefazolin sodium, by performing appropriate culture and susceptibility studies should be performed. (See MICROBIOLOGY for disc susceptibility tests and dilution techniques).

NOTE: Most strains of *Enterococci*, indole positive *Proteus* (P. vulgaris), *Enterobacter cloacae*, *Morganella morganii*, *Providencia rettgeri* and methicillin-resistant *Staphylococci* are resistant. *Serratia*, *Pseudomonas*, and *Acinetobacter calcoaceticus* (formerly *Mima* and *Herellea* species) are almost uniformly resistant to cefazolin. (See MICROBIOLOGY).

PERIOPERATIVE PROPHYLAXIS: In patients undergoing potentially contaminated surgical procedures, and in patients in whom infection would pose a serious risk (e.g., during open-heart surgery and prosthetic arthroplasty), the preoperative, intraoperative and postoperative administration of CEFAZOLIN INJECTION, USP may reduce the incidence of certain post-operative infections.

Identification of the causative organisms should be made by culture should signs of infection occur, so that appropriate therapy may be instituted.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of CEFAZOLIN INJECTION, USP and other antibacterial drugs, CEFAZOLIN INJECTION, USP should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

CEFAZOLIN INJECTION, USP is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

CEFAZOLIN INJECTION, USP should be used with caution in penicillin-allergic patients. There is clinical evidence of partial cross-allergenicity of the penicillins and the cephalosporins. There are instances of patients who have had reactions to both penicillins and cephalosporins (including fatal anaphylaxis after parenteral use). Clinical and laboratory evidence of partial cross-allergenicity of the two drug classes exists.

Cefazolin sodium should be administered cautiously and then only when absolutely necessary to any patient who has demonstrated allergy, particularly to drugs. Immediate emergency treatment with epinephrine is indicated for serious anaphylactoid reactions. As indicated, oxygen, intravenous steroids, and airway management, including intubation, should also be employed.

There have been reports of pseudo membranous colitis with the use of cephalosporins. It is therefore important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Solutions containing dextrose should be used with caution, if at all, in patients with known allergy to corn or corn products.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing CEFAZOLIN INJECTION, USP in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

PRECAUTIONS

The overgrowth of non-susceptible organisms may result from the prolonged use of CEFAZOLIN INJECTION, USP. It is essential that the patient be carefully observed.

In patients with a history of lower gastrointestinal disease, particularly colitis, cefazolin sodium should be prescribed with caution.

Clinitest^{R} tablets solution, but not enzyme-based tests such as Clinistix^{R} and Tes-Tape^{R,} may falsely indicate glucose in the urine of patients on cefazolin.

As with other dextrose-containing solutions, CEFAZOLIN INJECTION, USP should be prescribed with caution in patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

Positive direct and indirect Coombs' tests have been reported during treatment with cefazolin. These may also occur in neonates whose mothers received cephalosporins before delivery. The clinical significance of this effect has not been established.

Use in Renal Impairment:
Caution should be exercised in treating patients with pre-existing renal damage although cefazolin has not shown evidence of nephrotoxicity.

Patients with low urinary output due to impaired renal function should be administered reduced daily dosages of cefazolin. (See Dosage in Patients with Reduced Renal Function.) Blood levels of cefazolin in dialysis patients remain fairly high and should be monitored.

Probenecid may decrease renal tubular secretion of cefazolin when used concurrently with cefazolin sodium, resulting in increased and prolonged cefazolin blood levels.

In beta-haemolytic streptococcal infections, treatment should be continued for at least 10 days, to minimize possible complications associated with the disease.

Use in Pregnancy and Lactation:
The safety of the use of cefazolin sodium during pregnancy has not been established.

Lactation:
Very low concentrations of cefazolin are found in the milk of nursing mothers. Cefazolin sodium should be administered with caution to a nursing woman.

Children:
The safety of the use of cefazolin sodium in prematures and infants under one month of age has not been established.

Drug Interactions:
The renal tubular secretion of cefazolin may be decreased when probenecid is used concurrently, resulting in increased and prolonged cefazolin blood levels.

ADVERSE REACTIONS

The following reactions have been reported:

Gastrointestinal: Diarrhea, oral candidiasis (oral thrush), vomiting, nausea, stomach cramps, anorexia. During antibiotic treatment symptoms of pseudo membranous colitis can appear. There have been rare reports of nausea and vomiting.

Allergic: Allergic reactions occur infrequently and include: anaphylaxis, eosinophilia, itching, drug fever, skin rash.

Haematologic: Neutropenia, anemia, leukopenia, thrombocythemia, positive direct and indirect antiglobulin (Coombs') tests.

Hepatic and Renal: Without clinical evidence of renal or hepatic impairment transient increases in AST (SGOT), ALT (SGPT), BUN and alkaline phosphatase levels have been observed. Transient hepatitis and cholestatic jaundice have been reported rarely, as with some penicillins and some other cephalosporins.

Local Reactions: Phlebitis at the site of injection has occurred rarely. Some induration has been reported.

Other Reactions: Vulvar pruritus, genital moniliasis, vaginitis and anal pruritus.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

There is a lack of experience with acute cefazolin sodium overdosage. Supportive therapy should be instituted according to symptoms in cases of suspected overdosage.

DOSAGE AND ADMINISTRATION

DOSAGE
CEFAZOLIN INJECTION, USP in GALAXY Container (PL 2040 Plastic) is a premixed solution intended only for intravenous infusion. Administer CEFAZOLIN INJECTION, USP intravenously over approximately 30 minutes.

ADULTS:

Adult Dosage Guide

Type of Infection	Dose	Frequency
Mild infections caused by susceptible Gram-positive cocci	250 mg to 500 mg	Every 8 hours
Acute, uncomplicated urinary tract infections	1 g	Every 12 hours
Moderate to severe infections	500 mg to 1 g	Every 6 to 8 hours

Cefazolin sodium has been administered in dosages of 6 g per day in serious infections such as endocarditis.

Treatment should be continued for at least 10 days in beta-haemolytic streptococcal infections to minimize possible complications associated with the disease.

Dosage in Patients with Reduced Renal Function:
After an initial loading dose appropriate to the severity of the infection, the following reduced dosage schedule is recommended:

Dosage Guide for Patients with Renal Impairment

Creatinine Clearance (mL/s)	Serum Creatinine (mMol/L)	Dosage
≤0.91	≥140	250 mg to 1 g every 6-12 hours
0.58-0.9	141-273	250 mg to 1 g every 8-12 hours
0.18-0.57	274-406	125 mg to 500 mg every 12 hours
≤0.17	≥407	125 mg to 500 mg every 18 hours

Perioperative Prophylactic Use:
The recommended dosage regimen to prevent postoperative infection in contaminated or potentially contaminated surgery is:

a. One gram intravenously administered ½ hour to 1 hour prior to the start of surgery so that at the time of the initial surgical incision adequate antibiotic levels are present in the serum and tissues.
b. For lengthy operative procedures (e.g., 2 hours or more) 0.5-1 g administered intravenously during surgery. (Administration should be modified according to the duration of the operative procedure and the time of greatest exposure to infective organisms.)
c. Postoperatively, 0.5-1 gram intravenously every 6 to 8 hours for 24 hours postoperatively. The prophylactic administration of cefazolin sodium maybe continued for 3 to 5 days following the completion of surgery in which the occurrence of infection may be particularly devastating (e.g., open-heart surgery and prosthetic arthroplasty).

CHILDREN:

A total daily dosage of 25 to 50 mg per kg (approximately 10 to 20 mg per pound) of body weight, divided into three or four equal doses, is effective for most mild to moderately severe infections in children.

For severe infections total daily dosage maybe increased to 100 mg per kg (45 mg per pound) of body weight. The use of cefazolin in prematures and in infants under one month is not recommended since the safety for use in these patients has not been established.

Paediatric Dosage Guide – 25 mg/kg/day

Weight		25 mg/kg/day Divided Into 3 Doses		25 mg/kg/day Divided into 4 doses	
lb	**kg**	**Approximate Single Dose mg/q8h**	**Volume Needed of 20 mg/mL Solution**	**Approximate Single Dose mg/q6h**	**Volume Needed of 20 mg/mL Solution**
10	4.5	40 mg	2 mL	30 mg	1.5 mL
20	9	75 mg	3.75 mL	55 mg	2.75 mL
30	13.6	115 mg	5.75 mL	85 mg	4.25 mL
40	18.1	150 mg	7.5 mL	115 mg	5.75 mL
50	22.7	190 mg	9.5 mL	140 mg	7 mL

Paediatric Dosage Guide-50 mg/kg/day

Weight		50 mg/kg/day Divided Into 3 Doses		50 mg/kg/day Divided into 4 doses	
lb	**kg**	**Approximate Single Dose mg/q8h**	**Volume Needed of 20 mg/mL Solution**	**Approximate Single Dose mg/q6h**	**Volume Needed of 20 mg/mL Solution**
10	4.5	75 mg	3.75 mL	55 mg	2.75 mL
20	9	150 mg	7.5 mL	110 mg	5.5 mL
30	13.6	225 mg	11.25 mL	170 mg	8.5 mL
40	18.1	300 mg	15 mL	225 mg	11.25 mL
50	22.7	375 mg	18.75 mL	285 mg	14.25 mL

Treatment with 60 percent of the normal daily dose may be administered in divided doses every 12 hours to children with mild to moderate renal impairment (Ccr 0.67-1.17 mL/s). Children with moderate to severe renal impairment (Ccr 0.33- 0.87 mL/s) should be given 25 percent of the normal daily dose in equally divided doses every 12 hours, and children with severe renal impairment (Ccr 0.08-0.33 mL/s) should receive 10 percent of the normal daily dose every 24 hours.

All dosage recommendations apply after an initial loading dose.

ADMINISTRATION

DIRECTIONS FOR USE OF CEFAZOLIN INJECTION, USP IN GALAXY CONTAINER (PL 2040 PLASTIC)

CEFAZOLIN INJECTION, USP in GALAXY Container (PL 2040 Plastic) is to be administered either as a continuous or intermittent infusion using sterile equipment. Administer CEFAZOLIN

INJECTION, USP intravenously over approximately 30 minutes.

Storage
Store frozen bags in a freezer capable of maintaining a temperature of -20°C.

Thawing of Plastic Container
Thaw frozen container at room temperature (25°C) or under refrigeration (5°C). (**DO NOT FORCE THAW BY IMMERSION IN WATER BATHS OR BY MICROWAVE IRRADIATION.**)

Check for minute leaks by squeezing container firmly. If leaks are detected, discard solution as sterility may be impaired.

Do not add supplementary medication.

The container should be visually inspected. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired.

Components of the solution may precipitate in the frozen state and will dissolve upon reaching room temperature with little or no agitation. Potency is not affected. Agitate after solution has reached room temperature. If after visual inspection the solution remains cloudy or if an insoluble precipitate is noted or if any seals or outlet ports are not intact, the container should be discarded.

The thawed solution is stable for 30 days under refrigeration (5°C) and 48 hours at 25°C. **Do not refreeze thawed antibiotics**.

CAUTION: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is complete.

Preparation for administration
1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container
3. Attach administration set. Refer to complete directions accompanying set.

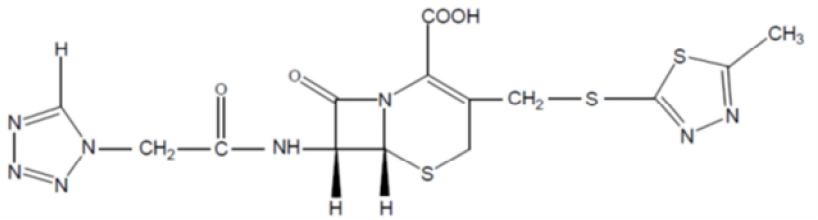
PHARMACEUTICAL INFORMATION

Drug Substance:

Proper Name: cefazolin acid

Chemical Name:
1. 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[[1H-tetrazol-1-yl)acetyl]amino]-(6R-trans)
2. (6R,7R)-3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[2-(1H-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2 carboxylic acid

Structural Formula



Molecular Formula: $C_{14}H_{14}N_8O_4S_3$

Molecular Weight: 454.51 g/mol

Description: Cefazolin acid is a white to off-white crystalline powder. Cefazolin acid meets the requirement of the current USP monograph for Cefazolin, USP.

Composition

CEFAZOLIN INJECTION, USP is a frozen, premixed, iso-osmotic, sterile, nonpyrogenic solution available in a single dose Galaxy container in two pack sizes:

Pack Size	Composition
50 mL	Cefazolin sodium equivalent to 1000 mg of Cefazolin, USP Dextrose, USP* (2 g as dextrose hydrous) Water for Injection, USP Sodium bicarbonate (for pH adjustment)
100 mL	Cefazolin sodium equivalent to 2000 mg of Cefazolin, USP Dextrose, USP* (4 g as dextrose hydrous) Water for Injection, USP Sodium bicarbonate (for pH adjustment)

* Dextrose, USP has been added to adjust osmolality

The solution is intended for intravenous use after thawing to room temperature.

The GALAXY container (PL 2040 Plastic) is fabricated from a specially designed multilayer plastic (PL 2040). Solutions are in contact with the polyethylene layer of this container and can leach out certain chemical components of the plastic in very small amounts within the expiration period. However, the suitability of the plastic has been confirmed in tests in animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies.

STABILITY AND STORAGE RECOMMENDATIONS

Store frozen bag at or below -20°C. [See DIRECTIONS FOR USE OF CEFAZOLIN INJECTION, USP IN GALAXY CONTAINER (PL 2040 PLASTIC).]

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

AVAILABILITY OF DOSAGE FORMS

CEFAZOLIN INJECTION, USP is supplied as a premixed frozen iso-osmotic solution in single-dose GALAXY plastic containers as follows:

1000 mg cefazolin in 50 mL supplied as 24 bags per carton
2000 mg cefazolin in 100 mL supplied as 12 bags per carton

MICROBIOLOGY

CEFAZOLIN ACTIVITY AGAINST CLINICAL ISOLATES

	No. of Strains	**Cumulative Percentage Susceptible to Strains Indicated Concentration (mcg/mL)**					
		<0.05	**<0.1 - 0.78**	**1.56 - 3.13**	**6.25 - 12.5**	**25 – 50**	**100**
S. AUREUS	700	0.14	59.1	90.6 – 92.4*	97.3	99.7	99.9
S. PYOGENES	5	80+	100				
S. FAECALIS	2				50	100	
S. PNEUMONIAE	6	100+					
E. COLI	484		8.7	67.9	92.1	95.9	97.7
P. MIRABILIS	30			50	86.7	90	90
K. PNEUMONIAE	138		2.9	53.6	73.2	91.3	93.5
ENTEROBACTER	31			6.5	29	64.5	77.4
H. INFLUENZAE	30			13.3	70	100	
N. GONORRHOEAE	13		38.5	100			
SHIGELLA SPP	2			50	50	100	
SALMONELLA SPP	8			100			
STAPHYLOCOCCI (coagulase - negative)	295		66	82	90	93	100

* Reported as 3.13-6.25 mcg/mL
\+ Reported as ≤ 0.1 mcg /mL

Disc Susceptibility Tests
The following criteria should be used to interpret tests using a standardized 30 mcg cephalosporin-class disc:

Zones of 18 mm or greater indicate that the tested organisms are susceptible and are likely to respond to therapy. Zones of 15 to 17 mm indicate organisms of intermediate susceptibility which may be susceptible if high dosage is used or if the infection is confined to tissues and fluids (e.g., urine) in which high antibiotic levels are attained. Zones of 14 mm or less are produced by resistant organisms.
The cephalothin disc should not be used for testing susceptibility to other cephalosporins.

Dilution Techniques: If the minimal inhibitory concentration (MIC) for cefazolin is not more than 16 mg/mL, then a bacterial isolate may be considered susceptible. If the MIC is equal to or greater than 64 mg/mL, organisms are considered to be resistant.
The ranges of MIC for the control strains were:
E. coli ATCC 25922 1-4 mg/mL
S. aureus ATCC 25923 0.25-1 mg/mL

PHARMACOLOGY

Clinical Pharmacology
The blood levels of cefazolin listed on the following table were determined following intravenous administration.

Serum Concentration (mcg/mL) Following Administration:

(Time After Intravenous Injection in Minutes)

	5	15	30	60	120	240
Cefazolin 1g	188.4	135.8	106.8	73.7	45.6	16.5

The serum half-life is approximately 1.8 hours following intravenous administration.
The mean peak serum levels of cefazolin in hospitalized patients are approximately equivalent to those seen in normal volunteers.
Healthy volunteers received a continuous intravenous infusion of 3.5 mg/kg for 1 hour (approximately 250 mg) and 1.5 mg/kg hourly for the next two hours (approximately 100 mg). A steady serum level of 28 mcg/mL was attained at the third hour.
Cefazolin levels in synovial fluid and serum are similar four hours after drug administration. Levels in cord blood are equivalent to 40% of those found in maternal blood.
In patients without obstructive biliary disease, serum levels of cefazolin can be up to five times lower than bile levels of cefazolin. However, bile levels of cefazolin are considerably lower than serum levels in patients with obstructive biliary disease.
Cefazolin is excreted unchanged in the urine. Approximately 60% of the drug is excreted in the first six hours, and this increases to 70%-80% within 24 hours.

TOXICOLOGY

Acute Toxicity
Parenteral and oral cefazolin demonstrated low toxicity in rodents, canines and rabbits tested in acute toxicity studies.

ACUTE TOXICITY

Species	Route of Administration	LD_{50} LD (g/kg)
Mice	intravenous	≥3.9
	intraperitoneal	≥4
	subcutaneous	7.6
	oral	>11
Rats	intravenous	≥3
	intraperitoneal	7.4
	subcutaneous	>10
	oral	>11
Rabbits	intravenous	>2
Dogs	intravenous	>2

Subacute and Chronic Toxicity

Rats and dogs were studied in subacute and chronic parenteral toxicity of cefazolin. Rats were treated for 3 and 6 months subcutaneously and for one month intraperitoneally. The highest doses ranged from 2000 mg/kg per day in the 6 month study to 4000 mg/kg per day in the 1 and 3 month studies. Anemia was the only significant abnormality attributable to s.c. drug administration. In all experiments there was a definite dose-related depression of SGPT levels. Leukocytosis and hypererythropoiesis accompanied the anemia, which was probably related to hemorrhaging at the injection site.

The lowering of the SGPT was dependent upon both the dose and the duration of treatment. This was not statistically significant at the low doses and was reversible upon withdrawal of the drug. Equivalent chronic studies in dogs produced similar results: at the higher doses there was a fall in SGPT and frank anemia resulted from high subcutaneous doses. Dogs treated intravenously did not develop the anemia indicating that it was probably associated with hemorrhaging at the site of injection.

Reproduction and Teratology

Rabbits and mice were administered cefazolin in doses of 240 mg/kg/day and 2400 mg/kg/day. No teratologic effects were observed. No adverse effects on mating, fertility, gestation, delivery and lactation were observed in rats administered 2000 mg/kg per day. Baby rats whose mothers were injected with 1200 mg/kg/day of cefazolin prior to delivery and throughout lactation were observed and there was no effect on the birth, or peri- and postnatal development.

Nephrotoxicity

The nephrotoxicity of cefazolin was studied following intravenous injections of rabbits and subcutaneous injections of mice and rats. The mean nephrotoxic intravenous dose in rabbits was between 300 and 400 mg/kg/day. No evidence of renal damage was produced when cefazolin was injected subcutaneously into mice at a dose of 8 g/kg/day for up to 3 days and into rats at a dose of 4 g/kg/day for up to 7 days.

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr CEFAZOLIN INJECTION, USP
Sterile cefazolin sodium solution

Read this carefully before you start taking CEFAZOLIN INJECTION, USP and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CEFAZOLIN INJECTION, USP.

What is CEFAZOLIN INJECTION, USP used for?
CEFAZOLIN INJECTION, USP is used for the treatment of infections caused by certain bacteria in many different parts of the body including the treatment of pneumonia.

CEFAZOLIN INJECTION, USP can also be used to prevent infections, before and after surgery.

Antibacterial drugs like CEFAZOLIN INJECTION, USP treat only bacterial infections. They do not treat viral infections.

How does CEFAZOLIN INJECTION, USP work?
CEFAZOLIN INJECTION, USP is an antibiotic, which belongs to a class of drugs called cephalosporins. CEFAZOLIN INJECTION, USP works by killing bacteria which cause infections in the body.

What are the ingredients in CEFAZOLIN INJECTION, USP?
Medicinal ingredients: cefazolin sodium
Non-medicinal ingredients: dextrose hydrous, water for injection, sodium bicarbonate (for pH adjustment)

CEFAZOLIN INJECTION, USP comes in the following dosage forms:
CEFAZOLIN INJECTION, USP comes as a frozen premixed solution (liquid) in a single dose GALAXY plastic container as follows:
1000 mg cefazolin in 50 mL GALAXY plastic container
2000 mg cefazolin in 100 mL GALAXY plastic container

Do not use CEFAZOLIN INJECTION, USP if:
- you have had an allergic reaction to CEFAZOLIN INJECTION, USP or other medicines such as cephalosporins.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CEFAZOLIN INJECTION, USP. Talk about any health conditions or problems you may have, including if you:
- have had an allergic reaction to penicillins
- have a history of bowel disease, particularly colitis
- have gallbladder problems
- have kidney problems with or without liver problems

- are pregnant or could become pregnant during treatment
- are breast feeding

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CEFAZOLIN INJECTION, USP:
- Probenecid used in the treatment of gout

How to take CEFAZOLIN INJECTION, USP:
- CEFAZOLIN INJECTION, USP will be given to you by your healthcare professional as an injection into the vein.
- Although you may feel better early in treatment, CEFAZOLIN INJECTION, USP should be used exactly as directed.
- Misuse or overuse of CEFAZOLIN INJECTION, USP could lead to the growth of bacteria that will not be killed by CEFAZOLIN INJECTION, USP (resistance). This means that CEFAZOLIN INJECTION, USP may not work for you in the future.
- Do not share your medicine.

Usual dose:
Your healthcare professional will decide how much CEFAZOLIN INJECTION, USP to give you and how often.

Overdose:

If you think you have been given too much CEFAZOLIN INJECTION, USP, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you miss an appointment to receive an injection of CEFAZOLIN INJECTION, USP, contact your healthcare professional as soon as possible.

What are possible side effects from using CEFAZOLIN INJECTION, USP?
These are not all the possible side effects you may feel when taking CEFAZOLIN INJECTION, USP. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:
- diarrhea, nausea, vomiting
- stomach cramps, loss of appetite
- rash, itching
- pain, tenderness or a hardened mass at the injection site
- vaginal and anal itching

CEFAZOLIN INJECTION, USP can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Anemia: fatigue, loss of energy, weakness, shortness of breath		√	
Hypersensitivity: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Liver disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
Oral candidiasis (yeast infection): creamy white bumps on the tongue, cheeks, gums or throat that bleed when scraped, pain, trouble swallowing, bad taste in the mouth		√	
Phlebitis: swelling of a vein near the injection site, with pain, tenderness, redness		√	
Platelet count increased: burning, redness, throbbing, numbness and/or tingling in the hands and feet, headache, dizziness, weakness, fainting, chest pain, vision changes		√	
Pseudomembranous colitis: watery, bloody diarrhea, mucus in the stool, abdominal cramps and pain, fever			√
Vulvovaginal mycotic infection: vaginal itching, burning during intercourse or urination, pain, redness, swelling, discharge		√	
White blood cell count decreased: infection, fatigue, fever, aches, pain, flu-like symptoms		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

How to store CEFAZOLIN INJECTION, USP:
CEFAZOLIN INJECTION, USP frozen bags will be stored by your healthcare professional at or below -20°C and thawed at room temperature prior to administration.
Keep out of reach and sight of children.

If you want more information about CEFAZOLIN INJECTION, USP:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website https://www.canada.ca/en/health-canada/services/drugs-health-products.html or by contacting the sponsor, Baxter Corporation, at:

  Baxter Corporation
  Mississauga, Canada L5N 0C2
  1-888-719-9955

This leaflet was prepared by Baxter Corporation.

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