PRODUCT MONOGRAPH

[Pr]JAMP Cephalexin

Cephalexin Tablets USP
250 mg and 500 mg

Antibiotic

JAMP Pharma Corporation
1310 rue Nobel
Boucherville, Québec
J4B 5H3

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PRODUCT MONOGRAPH

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250 mg and 500 mg

THERAPEUTIC CLASSIFICATION

Antibiotic

ACTION

Cephalexin is bactericidal against many gram-positive and gram-negative organisms. *In vitro* tests demonstrate that the cephalosporins are bactericidal through their inhibition of cell- wall synthesis[15].

INDICATIONS AND CLINICAL USES

JAMP Cephalexin (cephalexin) may be indicated for the treatment of bacterial infections of the respiratory tract [1,12][13,14], including otitis media [1,2], genitourinary tract [3], bone and joints [4,5], skin and soft tissue [6,7], when the infection is caused by susceptible organisms. Culture and susceptibility studies should be performed.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of JAMP Cephalexin and other antibacterial drugs, JAMP Cephalexin 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

JAMP Cephalexin (cephalexin) is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

Before therapy with JAMP Cephalexin (cephalexin) is instituted, careful inquiry should be made concerning previous hypersensitivity reactions to cephalosporins, penicillins or other drugs.

JAMP Cephalexin should be given only with caution to penicillin-sensitive patients. There is some evidence of cross-allergenicity between the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both.

Antibiotics including JAMP Cephalexin should be administered with caution, and then only when absolutely necessary, to any patient who has demonstrated some form of allergy, particularly to drugs. Of 12,917 clinical trial patients, 462 had histories of penicillin allergy [8]. Twenty-one of them (about 4.6 percent) were among those in whom possible allergic reactions to cephalexin were observed.

Gastrointestinal

Clostridium difficile-associated disease

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

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

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

Susceptibility/Resistance

Development of Drug-Resistant Bacteria

Prescribing JAMP Cephalexin 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

As is the case with all drugs, patients should be followed carefully so that adverse reactions or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to JAMP Cephalexin (cephalexin) occurs, the drug should be discontinued and the patient treated with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

Prolonged use of JAMP Cephalexin may result in overgrowth of non susceptible organisms.

Careful observation of the patient is essential. If super infection occurs during therapy, appropriate measures should be taken.

JAMP Cephalexin should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

If JAMP Cephalexin is to be used for long term therapy, periodic monitoring of hematology, renal and hepatic functions should be done.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy; e.g., the incision and drainage of abscesses.

Safety of this product for use during pregnancy has not been established.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

In patients being treated with JAMP Cephalexin, a false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with Clinitest tablets, but not with Tes- Tape® (Glucose Enzymatic Test Strip, USP).

ADVERSE REACTIONS

Of 12,917 patients treated with cephalexin in formal clinical trials, 771(6%) reported adverse events, of which 385 (3%) were judged to be drug related[8] . Four hundred and sixty-two of these patients had known sensitivity to penicillin, 4.6% reacted. The incidence of reported side effects is shown in Table 1.

TABLE 1
Adverse Events Reported in 12,917 Patients Treated With Cephalexin

	Relationship to Drug Probable/definite	Uncertain	Discontinued Treatment	Total Reports	Percent
Gastrointestinal					
Diarrhea	87	77	31	164	1.3
Nausea	72	62	24	134	1.0
Vomiting	38	44	24	82	0.6
Dyspepsia/G.I. upset	24	7	5	31	0.2
Abdominal cramp/pain	9	8	5	17	0.1
Anorexia	11	6	2	17	0.1
Hypersensitivity					
Skin rash	52	42	42	94	0.7
Urticaria	22	12	19	34	0.3
Central Nervous System					
Headache	7	11	6	18	0.1
Genitourinary					
Genital Moniliasis	42	11	6	53	0.8
Vaginitis	15	11	4	26	0.4
Pruritus Vulvae	10	5	-	15	0.2

Other adverse reactions experienced less frequently include: glossitis/stomatitis, oral moniliasis, pruritus ani, gastroenteritis, fever, pruritus, a positive direct Coombs', allergy/anaphylaxis, intertrigo, angioedema, dizziness, paresthesia, somnolence, visual hallucination/diplopia, insomnia, tremor, leucorrhea, dysuria, malaise/fatigue, super infection, myalgia/back pain, nuchal swelling, dyspnea, cardiac arrhythmia and vasodilatation.

One hundred and seventy patients (1.3%) had abnormal laboratory values. There was no consistent pattern of abnormality and only 2 patients were withdrawn from studies as a result of these findings.

TABLE 2
Abnormal Laboratory Values

	Relationship to drug			
	Probable/Definite	Uncertain	Total Reports	Percent
Hematological				
Eosinophilia	27	18	45	0.4
Biochemical				
Elev. Alk Phosphatase.	9	15	24	0.2
Elev. SGOT	11	21	32	0.3
Elev. SGPT	6	16	22	0.2
Renal				

Elev. BUN	3	11	14	0.1

Other abnormal values reported less frequently included: elevated creatinine, bilirubin and cholesterol; decreased platelets, hemoglobin and/or hematocrit.
The following adverse reactions have been reported during postmarketing experience:

Gastrointestinal: Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported.

Hypersensitivity: Allergic reactions in the form of rash, urticaria, angioedema, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary. Anaphylaxis has also been reported.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder. Reversible interstitial nephritis, eosinophilia, neutropenia, leukopenia, thrombocytopenia, and slight elevations in SGOT and SGPT have been reported.

Vertigo, tinnitus, hearing loss and behavioural changes in young children have been reported with cephalexin use.

OVERDOSAGE

Activated charcoal may be administered to aid in the removal of unabsorbed drug. General supportive measures are recommended.

Signs and Symptoms: Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea, and hematuria. If other symptoms are present, it is probably secondary to an underlying disease state, an allergic reaction, or toxicity due to ingestion of a second medication.

Treatment: Unless 5 to 10 times the normal dose of cephalexin has been ingested, gastrointestinal decontamination should not be necessary.

Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal.

Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cephalexin; however, it would be extremely unlikely that one of these procedures would be indicated.

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

DOSAGE AND ADMINISTRATION

JAMP Cephalexin (cephalexin) is administered orally. The adult dosage ranges from 1 to 4 g daily in divided doses. The usual adult dose is 1 g/day in divided doses every 6 hours. For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of JAMP Cephalexin greater than 4 g are required, parenteral cephalosporins, in appropriate doses should be considered. The recommended daily dosage for children is 25 to 50 mg/kg/day in divided doses every 6 hours.

For the treatment of bacterial pharyngitis caused by Streptococcus pyogenes group A, and, acute cystitis, the daily dosage may be divided into two and given every 12 hours.

In severe infections, the dosage may be doubled.

In the treatment of beta hemolytic streptococcal infections, JAMP Cephalexin therapy should be administered for at least ten days.

To obtain maximum peak levels, JAMP Cephalexin should be administered on an empty stomach.

PHARMACEUTICAL INFORMATION

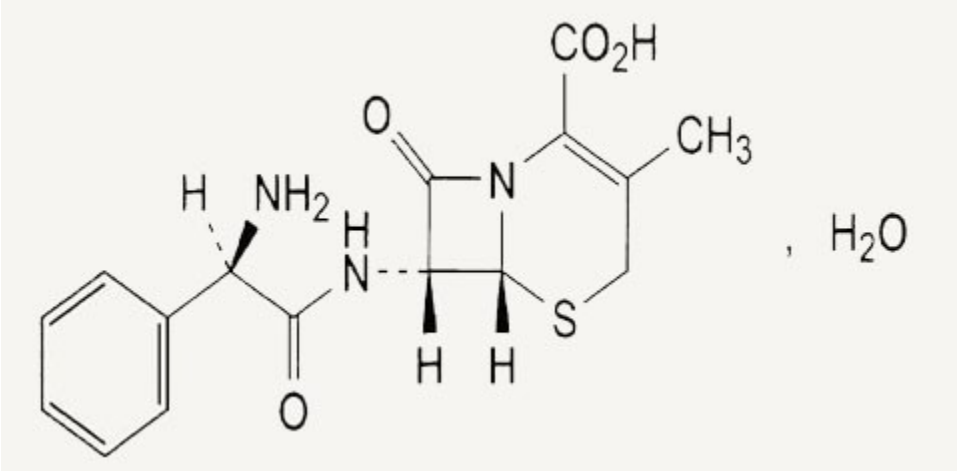
Drug Substance:

Proper Name: Cephalexin USP

Common Name: Cephalexin Monohydrate

Chemical Name: (6R,7R)-7-[[(2R)-2-amino-2-phenylacetyl]amino]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid monohydrate.

Structural Formula:



Molecular Formula: $C_{16}H_{17}N_3O_4S \cdot H_2O$

Molecular Weight: 365.40 g / mol

Description: Cephalexin monohydrate is a white to cream coloured crystalline powder with a characteristic odour. It is soluble in water to about 1.2% w/v at 25°C.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage form	Tablets	
	250 mg	500 mg
Description	Orange coloured, capsule shaped, biconvex film coated tablets embossed "CEP-250" on one side with partial score line and plain on other side.	Orange Coloured Capsule shaped, biconvex film coated tablets embossed "CEP 500" on one side with broken score line and plain on other side.
Composition	Medicinal ingredient: Cefalexin (as Cefalexin monohydrate). Non-Medicinal ingredients: Microcrystaline cellulose (Avicel PH 101), Microcrystaline cellulose (Avicel PH 102), Hydroxypropyl cellulose, Povidon K 30, polyethylene glycol 6000, Sodium starch glycolate type A, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, macrogol, FD&C YELLOW # 6, Maltodextrin, Modified Corn Starch, Natural & Artificial Flavors and Iron Oxide Red.	
Packaging	Both strengths are available in bottles of 100, 250, 500 and 1000 tablets.	

STORAGE RECOMMENDATIONS

Tablets:

Store between 15°C and 25°C. Avoid excessive heat (30°C). Protect from light and humidity. Keep well closed. Keep out of reach and sight of children.

CLINICAL TRIALS

Comparative Bioavailability Study

A double-blind, balanced, randomized, two-treatment, two-sequence, two-period, single oral dose, crossover, bioequivalence study of JAMP Cephalexin 500 mg tablets (JAMP Pharma Corporation) and [Pr] NOVO-LEXIN Cephalexin tablets USP 500 mg (Novopharm Limited) was conducted in 28 healthy, adult, human male subjects under fasting conditions. A summary of the comparative bioavailability data from the 25 subjects who completed the study is presented in the following table.

SUMMARY TABLE OF THE COMPARATIVE BIOAVAILABILITY DATA

Cephalexin (1 x 500 mg) From measured data Geometric Mean Arithmetic Mean (CV %)				
Parameter	Test* (N = 25)	Reference† (N = 25)	% Ratio of Geometric Means	90 % Confidence Interval
AUC_T (µg.h/mL)	45.22 45.87 (15.9)	47.56 48.14 (14.7)	95.1	92.3 – 98.0
AUC_I (µg.h/mL)	45.72 46.37 (15.7)	48.05 48.63 (14.5)	95.1	92.3 – 98.0
C_{max} (µg/mL)	21.10 21.97 (25.1)	25.51 26.23 (22.8)	82.7	75.9 – 90.2
T_{max}§ (h)	1.00 (0.75-2.27)	0.750 (0.50-1.50)		
$T_{½}$€ (h)	1.36 (13.0)	1.32 (10.2)		

* JAMP Cephalexin tablets, 500 mg (as cephalexin monohydrate) (JAMP Pharma Corporation, Canada)

† [Pr] NOVO-LEXIN tablets, 500 mg (as cephalexin monohydrate) (Novopharm Limited) was purchased in Canada.

§ Expressed as the median (range)

€ Expressed as the arithmetic mean (CV%) only.

MICROBIOLOGY

Cephalexin is active against the following organisms *in vitro*:
Beta-hemolytic and other streptococci (many strains of enterococci; e.g., *Streptococcus faecalis*, are resistant).
Staphylococci, including coagulase-positive, coagulase-negative, and penicillinase-producing strains (a few strains of staphylococci are resistant to cephalexin).

Streptococcus pneumonia	*Proteus mirabilis*
Escherichia coli	*Klebsiella pneumonia*
Hemophilus influenzae	*Branhamella catarrhalis*

Cephalexin is not active against most strains of Enterobacter sp., *Pr. morganii*, and *Pr. vulgaris*.
It has no activity against Pseudomonas or Herellea species. When tested by in vitro methods, staphylococci exhibit cross-resistance between KEFLEX® and methicillin-type antibiotics.

Table 3 shows the tube dilution sensitivity data as supplied by several investigators.

TABLE 3[(11)]
Susceptibility of Clinically Isolated Bacteria to Cephalexin Expressed as Cumulative Percent

MINIMUM INHIBITORY CONCENTRATION (mcg/mL)							
ORGANISM	NO. OF ISOLATES	≤2	2.5 - 4	5-8	10-16	20-32	40-64
Staph. aureus (unspecified)	458	31	58	81	92	97	99
Staph. aureus (penicillin-resistant)	158	41	82	88	98	99	100
Staph. aureus (penicillin-sensitive)	171	68	84	98	100	100	100
Staph. epidermidis	42	29	62	83	91	95	95
Str. pneumoniae	259	57	94	100	100	100	100
Str. pyogenes (group A)	262	84	91	96	99	100	100
E. coli	1165	1	9	40	76	88	92
Klebsiella sp.	533	1	9	55	78	86	88
Pr. mirabilis	535	-	3	14	56	77	84
H. influenzae	258	18	33	62	88	99	100
B. catarrhalis	14	64	100	100	100	100	100

PHARMACOLOGY

Animal

In the dog, there is evidence to show that cephalexin is absorbed primarily at the site of the duodenum. In dogs given 10 mg/kg of cephalexin intravenously, intramuscularly and orally, the blood serum level was approximately the same after 1 hour and 45 minutes[9]. Most of the drug is excreted in the urine. In rats, 5% of the administered dose was recovered in the bile. The serum half-life in rats and mice is 1.5 hours and 45 minutes respectively. Insignificant amounts enter the cerebrospinal fluid of dogs and monkeys. Variable amounts can be recovered from the breast milk of rats. Cephalexin distributes well to various tissues of rats, particularly the liver and kidney. (See Table 4).

TABLE 4
Cephalexin-^{14}C tissue levels in rats and in mice after a single oral dose of cephalexin-^{14}C (46 mcmoles/kg)

μg Cephalexin/g Tissue

TISSUE	RAT	RAT	MOUSE	MOUSE
	1 Hour	4 Hours	1 Hour	4 Hours
Blood	3.71	2.09	3.59	0.53
Liver	17.11	7.25	12.96	1.93
Spleen	2.21	1.45	1.45	0.4
Kidney	39.93	23.69	27.23	3.53
Lung	3.38	2.58	1.63	0.30
Heart	1.52	1.09	3.31	1.07
Fat	1.54	0.80	1.41	0.34
Muscle	1.16	0.76	1.11	0.32
Brain	0.53	0.24	0.30	0.11

Human:
Cephalexin is well absorbed orally to produce effective peak blood levels within 1 hour. (Figure 1)

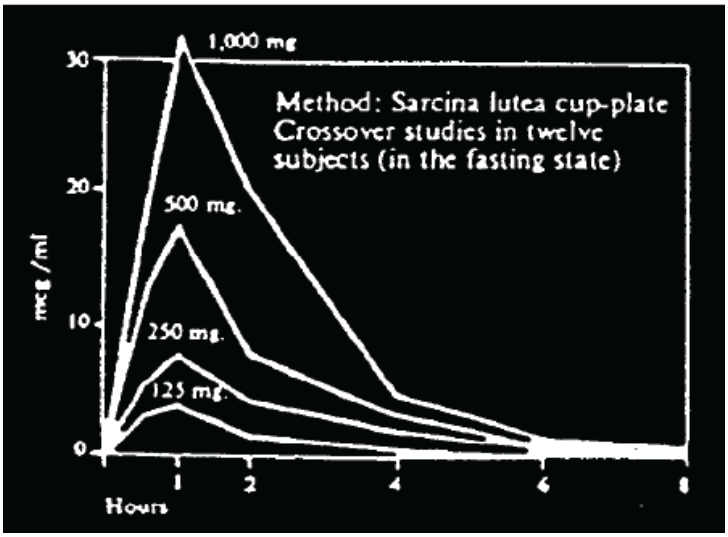


Figure 1 Cephalexin Blood Levels with Various Doses (Fasting Subjects)

Less than 10% of absorbed cephalexin is bound to serum protein in concentrations above 1g/mL (10). More than 80% is excreted as cephalexin in the urine. Reflex is acid stable. Food in the stomach causes a delay in onset, a lower peak and a prolongation of blood levels. Approximately 10% less cephalexin is excreted in the urine of patients taking food than in that of fasting subjects.

TOXICOLOGY

Acute Toxicity:

Table 5 summarizes the acute toxicity data(9), which indicate a low order of toxicity in mice, rats, cats, dogs, and monkeys when the drug is given orally. No toxicity was demonstrated until very high doses were reached. Only after single oral doses of 2 to 4.5 g/kg were employed in mice did lethargy or depression and anorexia persist for twenty-four hours. Diuresis was noted.

TABLE 5
Acute Toxicity of Cephalexin
LD_{50} (g/kg)

SPECIES	ORAL	INTRAPERITONEAL	INTRAVENOUS
Mouse	1.6-6.2	0.4-1.6	≥ 0.7
Rat	≥ 5.0 (LD_0)	≥ 3.65	≥ 0.7(LD_0)
(Weanling)	≥ 4.0		
(Newborn)	≥ 3.0		
Cat	≥ 1.0 (LD_0)	≥ 1.0	≥ 0.1(LD_0)
Dog	≥ 2.0 (LD_0)*	≥ 0.5 - ≥ 1.0	≥ 0.1(LD_0)

SPECIES	ORAL	INTRAPERITONEAL	INTRAVENOUS
Monkey	≥ 1.0 (LD_0)*		

* Emesis precluded a study of lethality in these species.

Although histological examination of the kidneys of animals that died revealed slight hydropic degeneration of the tubular epithelium, the cause or causes of death remain uncertain. Kidneys of some of the surviving animals showed regeneration in the tubular epithelium. Kidneys of the other mice surviving these high doses appeared normal. All blood chemistry parameters except BUN were unaffected by a 1000 mg/kg dose. The BUN concentrations increased to 200 mg in the mouse after 30 hours, but the concentrations at 72 hours were normal.

The rat was even less sensitive to cephalexin administered orally. All rats survived a 5 g/kg dose. Kidneys of these animals were found to be free of injury when examined microscopically.

In cats, dogs and monkeys, oral doses of 500 mg/kg produced salivation, emesis, and diarrhea; therefore a satisfactory study of the lethality in these species was precluded. Blood serum concentrations in the dogs and cats were as high as 200 g/mL after one and one-half hours. Twenty-four-hour trough levels were 4 g/mL or less.

A single oral dose of 400 mg/kg was well tolerated in the monkey.

From oral administration to animals, there was no indication that the pediatric formulation enhanced the toxicity of cephalexin. The largest practical dose, 40 mL/kg (1.0 g/kg), caused no deaths.

Intraperitoneal injections produced toxic effects similar to those seen after oral administration.

Subacute and Chronic Toxicity:
In animal toxicology studies, organic toxicity was not encountered at doses of 400 mg/kg administered over periods of one year.

The long-term safety of cephalexin was demonstrated in one-month studies in rats, dogs, and monkeys, and one-year studies in rats and dogs. The maximum daily doses of 1000 mg/kg for dogs and monkeys were well tolerated.

The only drug-related effects in the rats were transitory growth suppression, slight diarrhea of short duration, and enlargement of caecums and colons. The dogs developed transitory appetite suppression, salivation, occasional emesis, and occasional diarrhea. Histopathologic findings were normal, although blood concentrations were as high as 200 g/mL. Short-term studies showed that dogs can tolerate even larger doses (1000 to 2000 mg/kg) with salivation and emesis as the most serious side-effects. Salivation and moderate diarrhea were the only side-effects observed in monkeys.

Intravenous doses of 15 to 60 mg/kg/day of cephalexin were well tolerated for fourteen days by rats; dogs tolerated daily intravenous injections of 7.5 to 30 mg/kg. No apparent adverse effects were observed.

Reproduction and Teratology:

The fertility and reproduction of rats and mice were not affected by daily oral doses of cephalexin as great as 500 mg/kg. Skeletal abnormalities occurring in two out of twenty-two litters of mice included wavy ribs and varus limb conditions, but were not considered drug related(9). The survival of the rat progeny at twelve and twenty-one days of age was significantly less than that of the control animals in one study, but was similar to the control animals in another study.

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

[Pr] JAMP Cephalexin
(Cephalexin Tablets USP)
250 mg and 500 mg

Read this carefully before you start taking JAMP Cephalexin 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 JAMP Cephalexin.

What is JAMP Cephalexin used for?

- JAMP Cephalexin is used to treat certain bacterial infections in the:
  - respiratory tract;
  - ear (otitis media);
  - genitals and urinary tract;
  - bones and joints;
  - skin and soft tissue.
- Antibacterial drugs like JAMP Cephalexin treat only bacterial infections. They do not treat viral infections, such as the common cold.

How does JAMP Cephalexin work?

JAMP Cephalexin is an antibiotic that:

- Stops the growth of bacteria
- Kills bacteria

What are the ingredients in JAMP Cephalexin?

Medicinal ingredients: Cefalexin (cefalexin monohydrate)

Non-medicinal ingredients:

250 mg Tablets: Microcrystaline cellulose (Avicel PH 101), Microcrystaline cellulose (Avicel PH 102), Hydroxypropyl cellulose, Povidon K 30, polyethylene glycol 6000, Sodium starch glycolate type A, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, macrogol, FD&C YELLOW # 6, Maltodextrin , Modified Corn Starch , Natural & Artificial Flavors and Iron Oxide Red.

500 mg Tablets: Microcrystaline cellulose (Avicel PH 101), Microcrystaline cellulose (Avicel PH 102), Hydroxypropyl cellulose, Povidon K 30, polyethylene glycol 6000, Sodium starch glycolate type A, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, macrogol, FD&C YELLOW # 6, Maltodextrin , Modified Corn Starch , Natural & Artificial Flavors and Iron Oxide Red.

Do not use JAMP Cephalexin if:

- you are allergic to cephalexin, cephalosporin antibiotics or to any of the other ingredients in JAMP Cephalexin

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JAMP Cephalexin. Talk about any health conditions or problems you may have, including if you:

- you are allergic to or react badly to penicillins or other antibiotics.

- you have intestinal or bowel problems.
- you have kidney problems.
- you are pregnant or plan to be pregnant.
- you are breast-feeding or plan to breast-feed.

Other warnings that you should know about:

- Using antibiotics like JAMP Cephalexin may cause Clostridium difficile- associated disease (CDAD). See "Serious side effects and what to do about them", below.
- JAMP Cephalexin may interfere with some blood and urine test results. Talk to your doctor if you are given a blood or urine test while taking JAMP Cephalexin.

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

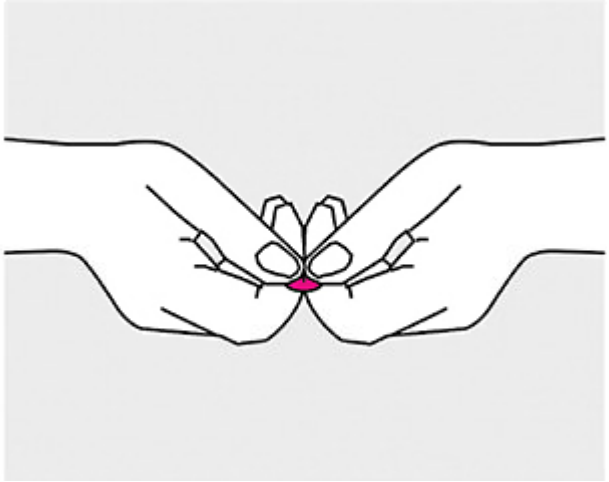
How to take JAMP Cephalexin:

- Take JAMP Cephalexin orally on an empty stomach.
- Although you may feel better early in treatment, JAMP Cephalexin should be used exactly as directed.
- Misuse or overuse of JAMP Cephalexin could lead to the growth of bacteria that will not be killed by JAMP Cephalexin (resistance). This means that JAMP Cephalexin may not work for you in the future.
- Do not share your medicine.

Usual dose:
Adult:
The adult dosage ranges from 1 to 4 g daily in divided doses. The usual adult dose is 1 g/day in divided doses every 6 hours.

Children:
The recommended daily dosage for children is 25 to 50 mg/kg/day in divided doses every 6 hours.

How to split JAMP Cephalexin 500mg:
Split each tablet manually by placing opposing thumbs (top) and index fingers (bottom) on opposite sides of the score line, and applying force.



Overdose:
Symptoms of oral overdose may include:

- nausea
- vomiting
- abdominal pain
- diarrhea
- bloody urine

If you think you have taken too much JAMP Cephalexin, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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

You may experience diarrhea, nausea, vomiting, loose stools, abdominal pain, diaper rash, inflammation of the vagina or discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations or symptoms that you do not understand. You should tell your health professional for of any of these symptoms as soon as possible.

Vertigo (loss of balance or unsteadiness), tinnitus (ringing in the ears), hearing loss and behavioural changes in young children have been reported.

JAMP Cephalexin may also cause effects such as yellowing of the whites of the eyes or skin (jaundice) or the inflammation of the liver (hepatitis).

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**	
RARE			
Symptoms of a severe bowel condition (*Clostridium difficile colitis*): • persistent diarrhea • bloody or watery diarrhea • abdominal or stomach pain/cramping • blood/mucus in stool			✓

Severe skin reactions: • skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) • widespread rash with blisters and skin peeling on much of the body surface particularly around the mouth, nose, eyes and genitals.			✓

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.

Storage:

Tablets:
Store between 15°C and 25°C. Avoid excessive heat (30°C). Protect from light and humidity. Keep well closed. Keep out of reach and sight of children.

If you want more information about JAMP Cephalexin:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp); or by calling 1-866-399-9091.

This leaflet was prepared by

JAMP Pharma Corporation
1310 rue Nobel
Boucherville, Québec
J4B 5H3

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