AUSTRALIAN PRODUCT INFORMATION

CEFALEXIN VIATRIS

(cefalexin monohydrate) capsules

1 NAME OF THE MEDICINE

Cefalexin monohydrate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains cefalexin monohydrate equivalent to 250 mg or 500 mg of cefalexin.

Excipients with known effect: sugars as lactose.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

CEFALEXIN VIATRIS 250 mg capsules: Dark green and white, self-locked hard gelatin capsules of size 2, imprinted with RX656 in black ink, containing white to off-white granular powder/pellets.

CEFALEXIN VIATRIS 500 mg capsules: Dark green and light green, self-locked hard gelatin capsules of size 0, imprinted with RX657 in black ink, containing white to off-white granular powder/pellets.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Treatment of the following bacterial infections when caused by susceptible strains of the designated microorganisms:

Respiratory tract infections:

Streptococcus pneumoniae and group A ß-haemolytic streptococci. Although penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections (including the prophylaxis of rheumatic fever), CEFALEXIN VIATRIS is generally effective in the eradication of streptococci from the nasopharynx. Substantial data establishing the efficacy of CEFALEXIN VIATRIS in the subsequent prevention of rheumatic fever are not available at present.

Bacterial sinusitis:

Streptococci, *Streptococcus pneumoniae* and *Staphylococcus aureus* (methicillin sensitive only).

Otitis media:

Streptococcus pneumoniae, *staphylococci* (methicillin sensitive only).

Skin and skin structure infections:

Staphylococci (methicillin sensitive only) and/or *streptococci*.

Genitourinary tract infections, including acute prostatitis:

E. coli, P. mirabilis and *Klebsiella sp.*

The effectiveness of cefalexin in the treatment of bacterial infections of the brain and spinal column has not been established and CEFALEXIN VIATRIS capsules are not indicated in these conditions.

Note: Appropriate culture and susceptibility tests should be initiated prior to and during therapy to determine susceptibility of the causative organism to CEFALEXIN VIATRIS capsules. Renal function studies should be performed when indicated.

4.2 DOSE AND METHOD OF ADMINISTRATION

Cefalexin is acid stable and may be given without regard to the administration of food. CEFALEXIN VIATRIS capsules are intended only for oral administration, at a usual dose frequency of three or four times daily.

Adults: The adult dosage ranges from 1 to 4 g daily in divided doses. The usual adult dose is 250 mg every six hours.

For streptococcal pharyngitis or tonsillitis, mild, uncomplicated urinary tract infections and skin and skin structure infections, a dosage of 500 mg may be administered every twelve hours.

For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of greater than 4 g are required, parenteral cephalosporins, in appropriate doses, should be considered.

Twice daily administration of CEFALEXIN VIATRIS capsules are not recommended when doses larger than 1 g daily are administered.

As with all antibiotics, treatment with CEFALEXIN VIATRIS capsules should continue for at least two days after the temperature has returned to normal and the symptoms have subsided.

4.3 CONTRAINDICATIONS

Previous history of hypersensitivity to cephalosporins or any of the excipients. Known allergy to the cephalosporin group of antibiotics or previous experience of a major allergy to penicillin (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

CEFALEXIN VIATRIS capsules are not indicated in the management of bacterial infections of the brain or spinal column.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

EXCEPT UNDER SPECIAL CIRCUMSTANCES, THIS MEDICATION SHOULD NOT BE USED WHEN THE FOLLOWING MEDICAL PROBLEM EXISTS:

- ALLERGIC REACTION (ANAPHYLAXIS)

BEFORE INSTITUTING THERAPY WITH CEFALEXCIN, EVERY ATTEMPT SHOULD BE MADE TO DETERMINE IF THE PATIENT HAS HAD PREVIOUS ALLERGIC REACTION (ANAPHYLAXIS) TO PENICILLINS, PENICILLIN DERIVATIVES, PENICILLAMINE, OR CEPHALOSPORINS OR OTHER MEDICINES.

There is some clinical and laboratory evidence of partial cross allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including ANAPHYLAXIS) to both drugs. Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to CEFALEXIN VIATRIS capsules occurs, the drug should be discontinued and the patient treated with the usual agents (e.g. adrenaline or other pressor amines, antihistamines or corticosteroids).

Prescribing cefalexin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Prolonged use of CEFALEXIN VIATRIS capsules may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Risk-benefit should be considered when the following medical problems exist:

Gastrointestinal disease

History of Colitis: Broad Spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic-associated colitis. As with other broad spectrum antibiotics, colitis, including rare instances of pseudomembranous colitis (see below), has been reported in conjunction with therapy with cefalexin.

Pseudomembranous colitis: Antibiotic associated pseudomembranous colitis has been reported with many antibiotics (such as macrolides, semisynthetic penicillins and cephalosporins) including cefalexin. A toxin produced with Clostridium difficile appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy).

Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against C. difficile should be considered. Fluids, electrolytes and protein replacement should be provided when indicated.

Drugs that delay peristalsis, e.g. opiates and diphenoxylate with atropine (e.g. Lomotil™) may prolong and/or worsen the condition and should not be used.

History of bleeding disorders: all cephalosporins may cause hypoprothrombinemia and, potentially, bleeding.

Dental: Long-term therapy with cephalosporins may allow for the overgrowth of Candida albicans resulting in oral candidiasis.

Neurotoxicity

There have been reports of neurotoxicity associated with cephalosporin treatment. Symptoms of neurotoxicity include encephalopathy, seizures and/or myoclonus. Risk factors for developing neurotoxicity with cephalosporin treatment include being elderly, renal impairment, central nervous system disorders and intravenous administration. Withdrawal of the medicine should be considered if there are signs of neurotoxicity. Anticonvulsant therapy can be given if clinically indicated.

Use in Hepatic Impairment

It is recommended that patients with severe liver disease receive a reduced dosage of cefalexin.

Use in Renal Impairment

Many cephalosporins are excreted renally. CEFALEXIN VIATRIS capsules should thus be administered with caution in the presence of markedly impaired renal function. Careful clinical and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Carnitine deficiency: *Some cephalosporins increase renal excretion of carnitine.*

Use in the Elderly

Cephalosporins have been used in the geriatric population, and no geriatrics-specific problems have been documented to date. However, elderly patients are more likely to have an age-related decrease in renal function, which may require an adjustment in dosage and/or dosing interval in patients receiving cephalosporins.

Paediatric Use

No data available.

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in patients taking beta-lactam antibiotics. When SCAR is suspected, CEFALEXIN VIATRIS should be discontinued immediately and an alternative treatment should be considered.

Effects on Laboratory Tests

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

A false positive reaction for glucose in urine may occur with Benedict's and Fehling's solutions and Clinitest tablets, but not with Tes-Tape. Quantitative determination of urinary excretion using strong acids is misleading as precipitation of cefalexin in the urine may occur.

Cefalexin can interfere with the Jaffle method of measuring creatinine, giving a falsely high reading; this should be borne in mind when measuring renal function.

Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Aminoglycoside antibiotics: renal function should be monitored carefully in patients receiving cephalosporins and aminoglycosides concurrently.

Anticoagulants, coumarin- or indandione-derivative, or Heparin or Thrombolytic agents: Because all cephalosporins can inhibit vitamin K synthesis by suppressing gut flora, prophylactic vitamin K therapy is recommended when any of these medications is used for prolonged periods in malnourished or seriously ill patients.

Platelet aggregation inhibitors: Hypoprothrombinemia induced by large doses of salicylates and/or cephalosporins, and the gastrointestinal ulcerative or hemorrhagic potential of nonsteroidal anti-inflammatory drugs [NSAIDs], salicylates, or sulfinpyrazone may increase the risk of haemorrhage.

Antacids or Ranitidine or Histamine H2-receptor antagonists: Concurrent use of high doses of antacids or H2-receptor antagonists or ranitidine may have effects on peak plasma levels of cephalosporins.

Probenecid: Probenecid decreases renal tubular secretion of those cephalosporins excreted by this mechanism, resulting in increased and prolonged cephalosporin serum concentrations, prolonged elimination half-life, and increased risk of toxicity.

Metformin: Concurrent administration resulted in increase of cefalexin serum concentration (34%) and reduced renal clearance by 14%. The renal clearance of metformin was reduced in a time-dependent manner in the presence of cefalexin. In healthy subjects given single 500 mg doses of cefalexin and metformin, plasma metformin C_{max} and AUC increased by an average of 34% and 24%, respectively, and metformin renal clearance decreased by an average of 14%. The interaction of cefalexin and metformin following multiple

dose administration has not been studied. Administration of a cephalosporin to a metformin-treated patient may result in increased metformin exposure.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

Adequate and well-controlled studies in humans have not been done.

However, studies in animals have not shown that cefalexin cause impaired fertility. In male and female rats, fertility and reproductive performance were not affected by cefalexin oral doses up to 1.5 times the highest recommended human dose based upon mg/m^2.

Use in Pregnancy (Category A)

Laboratory experiments with animals and clinical experience show no evidence of teratogenicity with cefalexin, but as with all drugs, CEFALEXIN VIATRIS capsules should be administered with caution during all stages of pregnancy.

Use in Lactation

Cefalexin is excreted in the milk. Caution should be exercised when CEFALEXIN VIATRIS capsules are administered to a breastfeeding woman. Alternative feeding arrangements for the infant should be considered.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse drug reactions reported with cefalexin are very rare (<0.01%) and are listed below:

Blood and the lymphatic system disorders:

Eosinophilia, neutropenia, thrombocytopenia, haemolytic anaemia

Gastrointestinal disorders:

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. The most frequent side effect has been diarrhoea, which may rarely be severe enough to warrant cessation of therapy with cefalexin. Nausea and vomiting have been reported rarely. Dyspepsia and abdominal pain have also occurred.

General disorders and administration site conditions:

Fatigue

Hepato-biliary disorders:

As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Slight elevations in AST and ALT have also been reported.

Immune system disorders:

Allergic reactions in the form of urticaria, angioedema and, rarely, These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Infections and Infestations:

Pseudomembranous Colitis

Musculoskeletal, connective tissue and bone disorders:

Arthralgia, arthritis and joint disorders.

Nervous system disorders:

Dizziness, headache, seizure

Encephalopathy, myoclonus (frequency not known)

Psychiatric Disorders:

Agitation, confusion, hallucinations

Renal and urinary disorders:

Reversible interstitial nephritis has been reported rarely.

Reproductive system and breast disorders:

Genital candidiasis, vaginitis, genital and anal pruritus, vaginal discharge

Skin and Subcutaneous Tissue Disorders

Rash, erythema multiforme

These reactions usually subsided upon discontinuation of the drug.

Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP), and symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome) have been reported in beta-lactam antibiotics.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at https://www.tga.gov.au/safety/reporting-problems.

4.9 OVERDOSE

Symptoms:

There is no definite experience of poisoning or severe overdosage with cefalexin. However, clinical features of overdosage may be similar to those seen with other cephalosporins and penicillins, i.e. convulsions, hallucinations, hyperreflexia, electrolyte imbalance, gastrointestinal disturbances, and haematuria.

Treatment:

In the event of severe overdosage, general supportive care is recommended including close clinical and laboratory monitoring of haematological, renal, hepatic functions and coagulation status until the patient is stable.

Forced diuresis, peritoneal dialysis, haemodialysis or charcoal haemoperfusion have not been established as beneficial for an overdose of cefalexin.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Cephalosporins have been classified by "generation" based on their spectrum of antibacterial activity. Cefalexin is reported as a first-generation cephalosporin.

Mechanism of Action

In vitro tests demonstrate that the Cephalosporins inhibit bacterial septum and cell wall synthesis, probably by acylation of membrane-bound transpeptidase enzymes. This prevents cross-linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity.

Cefalexin is active against following Aerobes, Gram-positive bacteria: Staphylococcus aureus including beta-lactamase–producing Staphylococci; and Streptococci (most species); exceptions include methicillin-resistant staphylococci and penicillin-resistant Streptococcus pneumoniae.

Note: Cefalexin is inactive against Enterococci or Listeria monocytogenes infections.

Aerobes, Gram-negative spectrum of cefalexin includes most Escherichia coli, Klebsiella species, Moraxella catarrhalis and Proteus mirabilis.

Note: Cefalexin is inactive against following Gram-negative aerobes: Serratia and Enterobacter or Pseudomonas species may induce beta-lactamases that inactivate the drug after a period of exposure to the cephalosporin, producing a resistance that may be expressed late; this resistance may not be detectable by disc sensitivity techniques. And none of the cephalosporin have useful activity against Bacteroides fragilis and related Gram-negative anaerobes.

Disc susceptibility tests

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (eg. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

- A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable.
- -A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small-uncontrolled technical factors from causing major discrepancies in interpretation.
- A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Minimal inhibitory concentration (MIC) breakpoints

Zone diameters, reported off cefalotin discs, are provided with corresponding breakpoints in Table 1.

Table 1 Cefalexin Susceptibility Testing Guidelines

Organisms	Zone diameter	MIC breakpoint**
Susceptible	≥18 mm	≤8 mcg/mL
Moderately susceptible	15-17 mm	1-16 mcg/mL
Resistant	≤14 mm	>16 mcg/mL

**Note: Quality control strains are needed to ensure that the procedure being run is consistent with expected results.

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Following oral administration, cefalexin is rapidly and almost completely absorbed.

Cefalexin is acid stable therefore CEFALEXIN VIATRIS capsules may be given without regard to meals. Peak serum concentrations are highly lower and are attained later when cefalexin is administered with food, although the total amount of drug is unchanged. The serum half-life of cefalexin is usually about one hour.

Average peak serum levels of approximately 9, 18 and 32 microgram/mL were obtained one hour following the oral administration of 250mg, 500mg and 1g doses respectively. Measurable levels of cefalexin may be present six hours after administration.

Absorption of cefalexin is delayed in young children and may be decreased up to 50% in neonates.

Distribution

Cefalexin crosses the placenta and small amounts are found in the milk of nursing mothers. The peak concentration in the breast milk after a dose of 500 mg oral dose is 4 microgram/mL.

Excretion

Cefalexin is excreted in the urine by glomerular filtration and tubular secretion. Over 90% of the drug is excreted unchanged in the urine within eight hours. During this period, reported peak urine concentrations following 250 mg, 500 mg and 1 g doses were approximately 1,000, 2,200 and 5,000 microgram/mL respectively.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Tests to determine the mutagenic potential of cefalexin have not been performed.

Carcinogenicity

Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of cefalexin.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

CEFALEXIN VIATRIS capsules contain the following the inactive ingredients: lactose, magnesium stearate, gelatin, iron oxide yellow, Brilliant blue FCF, Sunset yellow FCF, titanium dioxide, purified water, TekPrint SW-9008 black ink (ID 2328).

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light and moisture.

6.5 NATURE AND CONTENTS OF CONTAINER

CEFALEXIN VIATRIS 250 mg is in blister pack (PVC/PE/PVDC/Al) in pack size of 20 capsules.

CEFALEXIN VIATRIS 500 mg is in blister pack (PVC/PE/PVDC/Al) in pack size of 20 capsules.

Some strengths may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

AUST R 493733 – CEFALEXIN VIATRIS cefalexin 250mg capsule blister pack

AUST R 493735 – CEFALEXIN VIATRIS cefalexin 500mg capsule blister pack

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

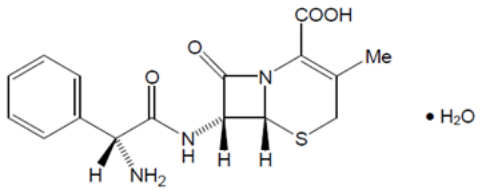
In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Cefalexin is a semisynthetic cephalosporin antibiotic intended for oral administration. Cefalexin is a white or almost white, crystalline powder. It is sparingly soluble in water and practically insoluble in alcohol.

Chemical Structure

Structural formula



Molecular formula: $C_{16}H_{17}N_3O_4S•H_2O$

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

Molecular weight: 365.4

CAS Number

23325-78-2

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

09/09/2025

10 DATE OF REVISION

26/11/2025

Summary Table of Changes

Section Changed	Summary of New Information
All	Minor editorial changes
6.5	Insert AUST R numbers
8	Update sponsor's details

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