PROFESSIONAL INFORMATION

SCHEDULING STATUS **S4**

1 NAME OF THE MEDICINE

CEPHALEXIN 250 PHARMA-Q capsules

CEPHALEXIN 500 PHARMA-Q capsules

CEPHALEXIN DRY SYRUP PHARMA-Q 125 mg/5 ml powder for oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

CEPHALEXIN 250 PHARMA-Q

Each capsule contains cefalexin monohydrate equivalent to anhydrous cefalexin 250 mg

Sugar free

CEPHALEXIN 500 PHARMA-Q

Each capsule contains cefalexin monohydrate equivalent to anhydrous cefalexin 500 mg

Sugar free

CEPHALEXIN DRY SYRUP PHARMA-Q

Each 5 ml of suspension contains cefalexin monohydrate equivalent to anhydrous cefalexin 125 mg

Preservative: Sodium Benzoate 0,2 % m/m

Contains sugar (sucrose): 2,304 g per 5 ml reconstituted suspension

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules

CEPHALEXIN 250 PHARMA-Q: Blue and white, locked, hard gelatine capsule, containing an off-white coloured powder. Shells are opaque.

CEPHALEXIN 500 PHARMA-Q: Red and white, locked, hard gelatine capsule, containing an off-white coloured powder. Shells are opaque.

Powder for oral suspension

CEPHALEXIN DRY SYRUP PHARMA-Q: Dry powder: Pink coloured, free flowing powder, with a flavour of peppermint and orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

CEPHALEXIN PHARMA-Q is used for the treatment of the following infections, caused by susceptible micro-organisms:

- Respiratory tract infections caused by *Streptococcus pneumoniae* and group A ß-haemolytic *streptococci*.
- Otitis media due to *Streptococcus pneumoniae*, *H. influenzae*, *staphylococci*, *streptococci* and *N. catarrhalis*.
- Skin and soft tissue infections caused by *staphylococci* and/or *streptococci*.
- Genito-urinary tract infections, including acute prostatitis caused by *E. coli*, *P. mirabilis* and *Klebsiella*.
- Dental infections caused by *staphylococci* and/or *streptococci*.

The susceptibility of causative organism to cefalexin should be determined by performing appropriate culture and susceptibility studies. When indicated, renal function studies should be performed.

4.2 Posology and method of administration

Posology

Adults: The adult dosage ranges from 1 g to 4 g daily in equally divided dose. The usual dose is 250 mg every 6 hours. For skin and soft tissue infections, Streptococcal pharyngitis and mild, uncomplicated urinary tract infections the usual dose is 250 mg every 6 hours, or 500 mg every 12 hours.

For more severe infections or infections caused by less susceptible organisms, larger doses may be needed. Parenteral therapy should be considered if daily doses higher than 4 g are required.

Elderly patients and patients with impaired renal function: The dosage is the same as for adults. If renal function is markedly impaired, reduce the dosage.

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

In the treatment of beta-haemolytic streptococcal infections, a therapeutic dose should be administered for at least 10 days.

Directions for mixing

For instructions on reconstitution of CEPHALEXIN DRY SYRUP PHARMA-Q powder for oral suspension before administration, see section 6.6.

Method of administration

Oral administration.

4.3 Contraindications

CEPHALEXIN PHARMA-Q is contraindicated in:

- Patients with known hypersensitivity to the cefalexin or any of the excipients of CEPHALEXIN PHARMA-Q (listed in section 6.1).
- Patients with known allergy to the cephalosporin group of antibiotics (see section 4.4).
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

Before therapy is instituted, enquiries should be made concerning previous hypersensitivity reactions to cephalosporins and penicillins or other medicines. CEPHALEXIN PHARMA-Q should be administered with caution to penicillin-sensitive patients. There is evidence of partial cross-allergenicity between penicillins and cephalosporins; patients have been reported to have severe reactions, including anaphylaxis to both medicines.

If an allergic reaction to cefalexin occurs CEPHALEXIN PHARMA-Q should be discontinued and the patient treated with the appropriate therapy.

There is a possibility of development of pseudomembranous colitis; therefore, it is important to consider its diagnosis in patients who develop diarrhoea in association with the use of cephalexin. Such colitis may be life-threatening and appropriate measures should be taken, including discontinuation of CEPHALEXIN PHARMA-Q.

Prolonged use of CEPHALEXIN PHARMA-Q may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential and appropriate measures should be taken if superinfection occurs during therapy.

Reports of neurotoxicity have been identified in association with cephalosporin treatment. Symptoms may include encephalopathy, myoclonus and seizures. Elderly patients, patients with severe renal impairment or central nervous system disorders are particularly at risk.

CEPHALEXIN PHARMA-Q should be administered with caution in the presence of impaired renal function and reduced dosage may be necessary. Reduced dosage is recommended in patients with severe renal impairment. Renal and haematological status should be monitored especially during prolonged and high-dose therapy.

CEPHALEXIN PHARMA-Q may interfere with the Jaffé method of measuring creatinine concentrations and falsely high values may be produced; this should be borne in mind when measuring renal function.

Positive direct Coombs' (antiglobulin) test has been reported during treatment with the cephalosporin antibiotics and these can interfere with blood cross-matching.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with cefalexin treatment. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, CEPHALEXIN PHARMA-Q should be withdrawn immediately.

CEPHALEXIN DRY SYRUP PHARMA-Q contains sugar (sucrose)

Patients with rare hereditary problems of fructose intolerance insufficiency should not take CEPHALEXIN DRY SYRUP PHARMA-Q.

4.5 Interaction with other medicines and other forms of interaction

Nephrotoxic medicines such as the aminoglycosides gentamicin and tobramycin may increase risk of kidney damage when used concomitantly with CEPHALEXIN PHARMA-Q. There is evidence for enhanced nephrotoxicity with the loop diuretic furosemide.

Probenecid delays urinary excretion of CEPHALEXIN PHARMA-Q.

The efficacy of oestrogen containing contraceptives may be decreased by CEPHALEXIN PHARMA-Q.

There may be antagonism between CEPHALEXIN PHARMA-Q and bacteriostatic antibacterials.

4.6 Fertility, pregnancy and lactation

The safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

CEPHALEXIN PHARMA-Q may cause dizziness or drowsiness or confusion. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

4.8 Undesirable effects

System Organ Class	Frequent	Description
Blood and the lymphatic system disorders	Frequent	Eosinophilia
	Less Frequent	Haemolytic anaemia, neutropenia and thrombocytopenia
Immune system disorders	Less Frequent	Hypersensitivity reactions, including skin rashes, urticaria, angioedema, eosinophilia, fever, reactions resembling serum sickness and anaphylaxis. Erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis
Psychiatric disorders	Frequency unknown	Agitation, hallucinations
Nervous system disorders	Frequent	Headache
	Less Frequent	Dizziness and drowsiness, convulsions and confusion have been associated with high doses, especially in patients with renal impairment
	Frequency	Tremor, myoclonia, encephalopathy,

System Organ Class	Frequent	Description
	unknown	hyperactivity, nervousness, sleep disturbances and hypertonia
Gastrointestinal disorders	Frequent	Nausea, vomiting and diarrhoea.
	Less Frequent	Abdominal cramps, pseudomembranous colitis, overgrowth of non-susceptible organisms
	Frequency unknown	Dyspepsia
Cardiac disorders	Frequency unknown	Kounis syndrome
Hepato-biliary disorders	Less Frequent	Hepatitis, cholestatic jaundice
Skin and subcutaneous tissue disorders	Frequency unknown	Acute generalised exanthematous pustulosis (AGEP). Linear IgA disease.
Musculoskeletal and connective tissue disorders	Frequency unknown	Arthralgia, arthritis and joint disorder
Renal and urinary disorders	Less Frequent	Nephrotoxicity, acute renal tubular necrosis, acute interstitial nephritis.
Reproductive system and breast disorders	Less Frequent	Vulval candidiasis
	Frequency unknown	Genital and anal pruritus, vaginitis and vaginal discharge
General disorders and administration site conditions	Less Frequent	Fatigue
Investigations	Less Frequent	Positive response to the Coombs' (antiglobulin) test, transient increases in liver enzyme values.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

See section 4.8 Undesirable effects. Treatment is symptomatic and supportive. Cefalexin is removed by haemodialysis and peritoneal dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.1.1 Broad and medium spectrum antibiotics.

Pharmacotherapeutic group: Antibacterials for systemic use, first-generation cephalosporins.

ATC code: J01DB

Cephalexin is a broad-spectrum, first-generation cephalosporin, bactericidal antibiotic. It exhibits its bactericidal action by inhibiting cell wall synthesis.

Cefalexin is active against Gram positive and Gram-negative organisms *in vitro*. Most strains of *enterococci* (*Streptococcus faecalis*) and a few strains of *staphylococci* are resistant to cefalexin. It is not active against most strains of *Enterobacter* species, *P. morganii* and *P. vulgaris*. It has no activity against *Pseudomonas* or *Herellea* species. When tested by *in vitro* methods, *staphylococci* exhibit cross-resistance between cefalexin and methicillin-type antibiotics.

In vitro sensitivity does not necessarily imply *in vivo* efficacy.

5.2 Pharmacokinetic properties

It is rapidly absorbed from the upper gastro-intestinal tract, giving peak levels at 1 hour and

following food at 2 hours. Following doses of 250 mg and 500 mg in adults, average serum levels of about 9 and 18 mcg per ml respectively were obtained at one hour. Over 90 % is recovered unchanged in urine within 8 hours. Peak urine concentrations are 1000 mcg per ml during this period following a 250 mg dosage of cefalexin.

The serum half-life of cefalexin is 0,9 to 1,2 hours but is prolonged in neonates. In uremic patients the half-life may increase to 5-30 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CEPHALEXIN 250 PHARMA-Q

Capsule contents:

- Dicalcium phosphate,
- gelatine,
- magnesium stearate.

Capsule shell:

- Brilliant blue,
- indigo carmine,
- titanium dioxide,
- gelatine.

CEPHALEXIN 500 PHARMA-Q

Capsule contents:

- Dicalcium phosphate,
- gelatine,
- magnesium stearate.

Capsule shell:

- Erythrosine,
- carmoisine,

- Ponceau 4R lake,
- titanium dioxide,
- gelatine.

CEPHALEXIN DRY SYRUP PHARMA-Q

- Sucrose,
- sodium benzoate,
- xanthan gum,
- peppermint flavour,
- orange flavour,
- colloidal anhydrous silica,
- colour erythrosine-lake.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Keep in a cool dry place at or below 25 ºC.

Keep the container tightly closed. Protect from light.

The reconstituted suspension must be used within 14 days if stored in a refrigerator or within 7 days if stored at or below 25 ºC.

6.5 Nature and contents of container

CEPHALEXIN 250 PHARMA-Q: Blister packs of 20 and 100 capsules

CEPHALEXIN 500 PHARMA-Q: Blister packs of 20 and 100 capsules

CEPHALEXIN DRY SYRUP PHARMA-Q: 50 g powder in an amber glass bottle for 100 ml suspension

6.6 Special precautions for disposal and other handling

Suspension: To prepare the solution: reconstitute 100 ml of suspension, add 67 ml of water, invert the bottle and shake until the powder is dispersed. The reconstituted suspension is a pink, homogenous suspension with a flavour characteristic of peppermint and orange

No special requirements for disposal.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Pharma-Q Holdings (Pty) Ltd

50 Commando Road,

Industria West 2093

Johannesburg

South Africa

info@pharmaq.co.za

Tel: 011 247 1600

8 REGISTRATION NUMBERS

CEPHALEXIN 250 PHARMA-Q: 29/20.1.1/0124

CEPHALEXIN 500 PHARMA-Q: 29/20.1.1/0125

CEPHALEXIN DRY SYRUP PHARMA-Q: 29/20.1.1/0126

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 October 1995

10 DATE OF REVISION OF THE TEXT

10 July 2026