SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT

Felexin 250 mg capsules
Felexin 500 mgcapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Felexin 250 mg capsules
Each capsule contains 250 mg Cefalexin (as Monohydrate).

Felexin 500 mg capsules
Each capsule contains 500 mg Cefalexin (as Monohydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Green/White capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Felexin is a semisynthetic cephalosporin antibiotic for oral administration.

Felexin is indicated in the treatment of the following infections due to susceptible micro-organisms:

- respiratory tract infections.
- otitis media.
- skin and soft tissue infections.
- bone and joint infections.
- genito-urinary tract infections, including acute prostatitis.
- dental infections.

4.2 Posology and method of administration

Posology

Adults: The adult dosage ranges from 1-4 g daily in divided doses; most infections will respond to a dosage of 500 mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis, and mild, uncomplicated urinary tract infections, the usual dosage is 250 mg every 6 hours, or 500 mg every 12 hours.

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

The elderly and patients with impaired renal function: As for adults. Reduce dosage if renal function is markedly impaired (see section 4.4, 'Special warnings and precautions for use').

Children: The usual recommended daily dosage for children is 25-50 mg/kg (10-20 mg/lb) in divided doses. For skin and soft tissue infections, streptococcal pharyngitis, and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours.
For most infections the following schedule is suggested:
Children under 5 years: 125mg every 8 hours.
Children 5 years and over: 250 mg every 8 hours.

In severe infections, the dosage may be doubled. In the therapy of otitis media, clinical studies have shown that a dosage of 75 to 100 mg/kg/day in 4 divided doses is required.

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

Method of administration
Cefalexin is administered orally.

4.3 Contraindications

Felexin is contra-indicated in patients known allergy to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

Before instituting therapy with cefalexin, every effort should be made to determine whether the patient has had previous hypersensitivity reactions to the cephalosporins, penicillins, or other drugs. Cefalexin should be given cautiously to penicillin-sensitive patients. There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and cephalosporins. Patients have had severe reactions (including anaphylaxis) to both drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics, including macrolides, semi-synthetic penicillins, and cephalosporins. It is important, therefore, to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.

If an allergic reaction to cefalexin occurs, the drug should be discontinued and the patient treated with the appropriate agents.

Prolonged use of cefalexin 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.

Cefalexin should 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. If dialysis is required for renal failure, the daily dose of cephalexin should not exceed 500 mg.

Concurrent administration with certain other drug substances, such as aminoglycosides, other cephalosporins, or furosemide (frusemide) and similar potent diuretics, may increase the risk of nephrotoxicity.

Positive direct Coombs' tests have been reported during treatment with the 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 newborns 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 the urine may occur with Benedict's or Fehling's solutions, or with copper sulphate test tablets. Cefalexin may interfere with the alkaline picrate assay for creatinine.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with cefalexin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, cefalexin should be withdrawn immediately and an alternative treatment considered. Most of these reactions occurred most likely in the first week during treatment.

4.5 Interaction with other medicinal products and other forms of interaction

As with other beta-lactam drugs, renal excretion of cefalexin is inhibited by probenecid.

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%. No information is available about the interaction of cefalexin and metformin following multiple dose administration..

Hypokalaemia has been described in patients taking cytotoxic drugs for leukaemia when they were given gentamicin and cephalexin.

4.6 Fertility, pregnancy and lactation

Pregnancy
Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing Felexin in pregnant women.

LactationThe excretion of cefalexin in human breast milk increased up to 4 hours following a 500 mg dose. The drug reached a maximum level of 4micrograms/ml, then decreased gradually and had disappeared 8 hours after administration. Caution should be exercised when cefalexin is administered to a nursing woman, since the neonate is presented with the risk of

candidiasis and CNS toxicity due to immaturity of the blood-brain barrier. There is a theoretical possibility of later sensitisation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Gastro-intestinal: Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side-effect has been diarrhoea. 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 rarely.

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

Haemic and lymphatic system: Eosinophilia, neutropenia, thrombocytopenia, and haemolytic anaemia have been reported.

Skin and subcutaneous tissue disorders (frequency: not known): Acute generalized exanthematous pustulosis (AGEP).

Other: These have included genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder. Reversible interstitial nephritis has been reported rarely. Slight elevations in AST and ALT have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 via the national reporting system.

4.9 Overdose

Symptoms of oral overdose may include nausea, vomiting, diarrhoea, epigastric distress and haematuria.
In the event of severe overdosage, general supportive care is recommended, including close clinical and laboratory monitoring of haematological, renal, and 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. It would be extremely unlikely that one of these procedures would be indicated.

Unless 5 to 10 times the normal total daily dose has been ingested, gastro-intestinal decontamination should not be necessary.

There have been reports of haematuria, without impairment of renal function, in children accidentally ingesting more than 3.5 g of cefalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use; Other beta-lactam antibacterials, ATC code: J01DB01

In vitro tests demonstrate that cephalosporins are bactericidal because of their inhibition of cell was synthesis.

Cefalexin is active against the following micro-organisms *in vitro*:

- *Beta-haemolytic streptococci.*
- *Staphylococci,*including coagulase-positive, coagulase-negative and penicillinase-producing strains.
- *Streptococcus pneumoniae.*
- *Escherichia coli.*
- *Klebsiella species.*
- *Proteus mirabilis.*
- *Haemophilus influenzae.*
- *Branhamella catarrhalis.*

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, *Morganella morganii*, and *Pr. vulgaris*. It has no activity against *Pseudomonas* or *Herellea* species or *Acinetobacter calcoaceticus*. Penicillin-resistant *Streptococcus pneumoniae* is usually cross-resistant to beta-lactam antibiotics. When tested by *in vitro* methods, staphylococci exhibit cross-resistance between cefalexin and methicillin-type antibiotics.

5.2 Pharmacokinetic properties

Cefalexin is acid stable. Cefalexin is almost completely absorbed from the gastro-intestinal tract, and 75-100% is rapidly excreted in active form in the urine. Absorption is slightly reduced if the drug is administered with food. The half-life is approximately 60 minutes in patients with normal renal function. Haemodialysis and peritoneal dialysis will remove cefalexin from the blood.

Peak blood levels are achieved one hour after administration, and therapeutic levels are maintained for 6-8 hours. Approximately 80% of the active drug is excreted in the urine within 6 hours. No accumulation is seen with dosages above the therapeutic maximum of 4 g/day.

The half-life may be increased in neonates due to their renal immaturity, but there is no accumulation when given at up to 50 mg/kg/day.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content
Sodium starch glycolate (Type A)
Sodium laurilsulfate
Silica, colloidal anhydrous
Magnesium stearate

Capsule shell
Titanium dioxide E171
Gelatin
Patent blue V E131
Quinoline yellow E104

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store below 25 ºC.Protect from light and moisture.

6.5 Nature and contents of container

Felexin 250 mg capsules
PVC/Aluminium Blisters. Pack sizes of 20 and 100 capsules.
PP containers with PE closures. Pack sizes of 500 and 1000 capsules.

Felexin 500 mg capsules
PVC/Aluminium Blisters. Pack sizes of 16, 20, 100 and 1000 capsules.
PP containers with PE closures. Pack sizes of 500 and 1000 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Remedica Ltd
Aharnon Street, Limassol Industrial Estate
3056 Limassol
Cyprus

8. MARKETING AUTHORISATION NUMBER(S)

Felexin 500 mg capsules: 05182/07259/REN/2020 , 06744/07435/VAR/2021

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of latest renewal: Jun 19, 2020

10. DATE OF REVISION OF THE TEXT

04/07/2023