SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

FEZINE Dry Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml when reconstituted with water contains: Cephalexin BP Equivalent to Cephalexin Anhydrous base: 125 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

For oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication

Fezine Dry Syrup is indicated for the treatment of Infections caused by susceptible organisms.

4.2 Posology and method of administration

Posology

- 250 mg every 6 hours or 500 mg every 8-12 hours increased to 1-1.5 g every 6-8 hours for severe infections; - Child: 25 mg/kg daily in divided doses, doubled for severe infections, max. 100 mg/kg daily; or under 1 year 125 mg - every 12 hours, 1-5 years 125 mg every 8 hours, 5-12 years 250 mg every 8 hours. - Prophylaxis of recurrent urinary- tract infection, adult 125 mg at night. Suspension Add freshly boiled and cooled water upto the mark. Shake vigorously. Adjust the volume with water upto the mark if required.

Method of administration

Oral

4.3 Contraindications

Patients who are known or suspected to be allergic to other cephalosporins should not be treated with Cephalexin.

4.4 Special warnings and precautions for use

Any patient who has a relative with porphyria should be screened and advised about the potential for cephalosporins to induce acute porphyric crises.

Cephalexin should be given cautiously to patients who have shown hypersensitivity to other drugs. Cephalosporins should

be given with caution to penicillin-sensitive patients, as there is some evidence of partial cross-allergenicity between 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, semisynthetic 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 the patient experiences an allergic reaction Cephalexin should be discontinued and treatment with the appropriate agents initiated.

Prolonged use of Cephalexin 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.

Cephalexin should be administered with caution in the presence of markedly impaired renal function as it is excreted mainly by the kidneys. Careful clinical and laboratory studies should be made because the safe dosage may be lower than that usually recommended.

Positive direct Coombs' tests have been reported during treatment with cephalosporin antibiotics. For 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. Tests based on glucose oxidation reactions may be safely used.

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with Cephalexin 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, Cephalexin 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 cephalosporins like Cephalexin are only active against proliferating microorganisms, they should not be combined with bacteriostatic antibiotics.

Concomitant use of uricosuric drugs (e.g. probenicid) suppresses renal drug elimination. As a result, Cephalexin plasma levels are increased and sustained for longer periods.

If associated with highly potent diuretics (ethacrynic acid, furosemide) or other potentially nephrotoxic antibiotics (aminoglycosides, polymyxin, colistin), cephalosprins may show higher nephrotoxicity.

Combined use of cephalosporins and oral anticoagulants may prolong prothrombin time.

A potential interaction between Cephalexin and metformin may result in an accumulation of metformin and could result in fatal lactic acidosis.

Hypokalaemia has been described in patient 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 for the pregnant patient.

Breast-feeding
The excretion of Cephalexin in human breast milk increased up to 4 hours following a 500mg dose. The drug reached a maximum level of 4 micrograms/ml, then decreased gradually and had disappeared 8 hours after administration. Caution should be exercised when Cephalexin is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

When driving vehicles or operating machines it should be taken into account that occasionally dizziness, tiredness or confusion may occur.

4.8 Undesirable effects

Side effects of Cephalexin include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea and abdominal discomfort. The most common of these effects is diarrhoea, but this is rarely severe enough to warrant cessation of therapy. Dyspepsia has also occurred. Transient hepatitis and cholestatic jaundice have rarely been reported.

Allergic reactions have been reported such as rash, urticaria,

angioedema and rarely erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (exanthematic necrolysis). These reactions usually subsided upon discontinuation of the drug, although in some cases supportive therapy may be necessary. Anaphylaxis and Acute generalised exanthematous pustulosis (AGEP) have also been reported.

Other side effects such as genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis and joint disorders have been reported.
As with other cephalosporins interstitial nephritis has rarely been reported.

Eosinophilia, neutropenia, thrombocytopenia, haemolytic anaemia and slight elevations in AST and ALT have been reported.

As with other broad-spectrum antibiotics prolonged use may result in the overgrowth of non-susceptible organisms, e.g. candida. This may present a vulvo-vaginitis.

There is a possibility of development of pseudomembranous colitis and it is therefore important to consider its diagnosis in patients who develop diarrhoea while taking Cephalexin. It may range in severity from mild to life threatening with mild case usually responding to cessation of therapy. Appropriate measures should be taken with moderate to severe cases.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhoea and haematuria. General management consists of close clinical and laboratory monitoring of haematological, renal and hepatic functions and coagulation status until the patient is stable.

Serum levels of Cephalexin can be considerably reduced by haemodialysis or peritoneal dialysis.

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 3.5g of Cephalexin 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, First-generation Cephalosporins.
ATC code: J01DB01

Cephalexin inhibits bacterial cell wall synthesis, probably by acylation of the membrane-bound enzyme transpeptidase. This prevents cross-linkage of peptidoglycan chains which is necessary for bacterial cell wall strength and rigidity. Cell division and growth are also inhibited and lysis of susceptible bacteria frequently occurs. Cephalexin is active in vitro against both Gram-positive and Gram-negative micro-organisms. (in vitro sensitivity does not necessarily imply in vivo efficacy). Group A Streptococcus pyogenes, the viridans group, and non-haemolytic streptococci, Streptococcus (D) pneumoniae, penicillin-resistant and penicillin-sensitive Staphylococcus aureus, Staphylococcus epidermis, Clostridium perfringes, B. subtilis, C. diphtheriae, N. gonorrhoeae, N. meningitides, and A israeli are highly sensitive to this agent, many being suppressed by concentrations of 0,004 to 1 ug/mL. Gram-negative bacteria are generally less susceptible, but the majority strains of Salmonella, including S. typhi, most Shigella, all Pr mirabilis, and about 75% of E. coli, 60% of paracolon strains are inhibited by 1 to 6 ug/mL. Indole, producing strains of Proteus Enterobacter (Aerobacter), Pseudomonas, and an occasional strain of Klebsiella are highly resistant to Cephalexin. Enterococci and H. influenzae are also insensitive to the drug.

5.2 Pharmacokinetic properties

Cephalexin is almost completely absorbed from the gastrointestinal tract and produces peak plasma concentrations about 1 hour after administration.

A dose of 500 mg produces a peak plasma concentration of about 18 □g per ml; doubling the dose doubles the peak concentration. Cephalexin readily diffuses into tissues, including bone, joints and the pericardial as well as pleural cavities. Only 10-15% of the dose is bound to plasma proteins. Elimination is mainly renal with 80% of the dose, recovered from the urine, therapeutically active, in the first 6 hours. Cephalexin does not enter cerebrospinal fluid in significant quantities. Cephalexin crosses the placenta and small quantities are found in the milk of nursing mothers. Therapeutically effective concentrations may be found in the bile and some may be excreted by this route.

The half-life has been reported to range from 0.5 to 2 hours and this increases with reduced renal function.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline
Cellulose Granules IHS
Anhydrous Dextrose BP
Purified Talc BP Colour
Brilliant Blue FCF IHS
Colour Tartrazine IHS
Flavour Pineapple Dry
IHS Flavour Mixed Fruit
Dry IHS Flavour Sweet
Orange Dry IHS
Colloidal Anhydrous
Silica BP Xanthan Gum
USP-NF Citric Acid Mon

6.2 Incompatibilities

There are no known incompatibilities.

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Do not store the granules for oral suspension above 25°C.
- Store the reconstituted oral suspension at 2 – 8°C (in a refrigerator)
- Keep the container closed.

6.5 Nature and contents of container

HDPE Bottle.

6.6 Special precautions for disposal and other handling

None applicable.

7 MARKETING AUTHORISATION HOLDER

Medcure Healthcare Limited, Kensia House, Muranga Road S002 and 15, P.O Box 14609-00400, Tom Mboya Street, Nairobi, Kenya.

Manufacturing site:

Saga Laboratories Ltd, Survey no. 198/2 & 198/3, Chachrawadi, NR Claris, TA Sanand, Dist: Ahmedbad, India.

8 MARKETING AUTHORISATION NUMBER(S)

H2021/CTD7569/14736

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 September 2021

10 DATE OF REVISION OF THE TEXT

20/08/2026