For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

PHEXIN

1. GENERIC NAME

Generic names of different *PHEXIN* formulations are provided in Section 2. Below.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Extended Release Tablets

PHEXIN BD Tablets 375 (Cephalexin Long Acting Tablets 375 mg)

Each long acting film-coated tablet contains:
Cephalexin IP equivalent to anhydrous Cephalexin 375 mg
Colours: Ferric Oxide USPNF (Red) and Titanium Dioxide IP

PHEXIN BD Tablets 750 (Cephalexin Long Acting Tablets 750 mg)

Each long acting film-coated tablet contains:
Cephalexin IP equivalent to anhydrous Cephalexin 750 mg
Colours: Ferric Oxide USPNF (Red) and Titanium Dioxide IP

List of Excipients

Microcrystalline Cellulose, Hypromellose (K4MCR), Hydroxypropyl Cellulose - M, Hypromellose (5 Cps), Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica, Opadry Oy-54956 Pink (includes Ferric Oxide (Red) and Titanium Dioxide), Opacode Black S-1-17823, Isopropyl Alcohol, Purified Water.

Hard Gelatin Capsules

PHEXIN (Cephalexin Capsules IP 250 mg)

Each capsule contains:
Cephalexin IP equivalent to anhydrous Cephalexin 250 mg
Approved colours used in empty capsule shell q.s.

PHEXIN (Cephalexin Capsules IP 500 mg)

Each capsule contains:
Cephalexin IP equivalent to anhydrous Cephalexin 500 mg
Approved colours used in empty capsule shell q.s.

List of Excipients

Cephalexin Capsules IP 250 mg: Magnesium Stearate, Colours (in empty capsule shells)
Cephalexin Capsules IP 500 mg: Magnesium Stearate, Colours (in empty capsule shells)

Dispersible Tablets

PHEXIN KID TABLETS DISPERSIBLE TABLETS (Cephalexin Tablets IP 125 mg)

Each uncoated dispersible tablet contains:
Cephalexin IP equivalent to anhydrous Cephalexin 125 mg
Colour: Sunset Yellow FCF.

PHEXIN DISPERSIBLE TABLETS (Cephalexin Tablets IP 250 mg)

Each uncoated dispersible tablet contains:
Cephalexin IP equivalent to anhydrous Cephalexin 250 mg
Colour: Sunset Yellow FCF.

List of Excipients

Magnesium Stearate, Colour Sunset Yellow FCF, Flavour Trusil Orange, Pregelatinised Starch, Microcrystalline Cellulose, Crospovidone, Monoammonium Glycyrrhizinate, Sodium Starch Glycollate, Purified Talc, Purified Water.

Oral Suspension

PHEXIN REDISYP 125mg / 5ml (Cephalexin Suspension 125 mg / 5 ml)

Each 5 ml contains:
Cephalexin IP equivalent to 125 mg of anhydrous Cephalexin in a flavoured base
Colour: Quinoline Yellow Lake.

List of Excipients

Polysorbate 80, Xanthan Gum, Microcrystalline Cellulose, Aerosil 200, Aspartame, Disodium Edetate, Sucrose, Quinoline Yellow Lake, Flavour Pineapple, Vanillin, Butylated Hydroxytoluene, Corn Oil.

PHEXIN REDISYP 250mg / 5ml (Cephalexin Suspension 250 mg / 5 ml)

Each 5 ml contains:
Cephalexin IP equivalent to 250 mg of anhydrous Cephalexin in a flavoured base
Color: Quinoline Yellow Lake.

List of Excipients

Polysorbate 80, Xanthan Gum, Microcrystalline Cellulose, Aerosil 200, Aspartame, Disodium Edetate, Sucrose, Quinoline Yellow Lake, Flavour Banana, Butylated Hydroxytoluene, Corn Oil.

Powder for Oral Suspension

PHEXIN SUSPENSION (For Paediatric Use) (Cephalexin for Oral Suspension IP 250mg/5ml)

Each 5 ml of the reconstituted suspension contains:

Cephalexin IP equivalent to anhydrous Cephalexin 250 mg
Color: Sunset Yellow FCF.

List of Excipients

Acacia powder, Citric Acid Anhydrous, Colour Sunset Yellow FCF, Edetate Calcium disodium, Flavour Trusil Orange, Sodium Citrate, Sucrose, Isopropyl alcohol.

PHEXIN PEDIATRIC DROPS* (*Cephalexin for Oral Suspension IP 100mg/ml)

Each 1 ml of the reconstituted suspension contains:
Cephalexin IP equivalent to anhydrous Cephalexin 100 mg
Colour: Sunset Yellow FCF.

List of Excipients

Acacia powder, Citric Acid Anhydrous, Colour Sunset Yellow FCF, Edetate Calcium disodium, Flavour Trusil Orange, Sodium Citrate, Sucrose, Isopropyl alcohol.

3. DOSAGE FORM AND STRENGTH

Details provided above in *Section 2. Qualitative and Quantitative Composition*

4. CLINICAL PARTICULARS

4.1. Therapeutic Indication

Cephalexin is a bactericidal antibiotic which is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for treatment of the following conditions, when caused by susceptible bacteria.

It is indicated for treatment of respiratory tract infections (RTIs), urinary tract infections (UTIs), skin and soft tissue infections, otitis media and other infections (including dental infections) due to sensitive organisms.

4.2. Posology and Method of Administration

For oral use.

Each capsule should be swallowed whole with water.

Extended release tablets should not be divided, crushed, powdered or chewed but should be swallowed whole with a glass of water, after meals.

Populations

Adults

Oral Formulations (other than Extended Release Tablets)

The dosage is 1- 4 g daily in divided doses. Most infections will respond to 500 mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild uncomplicated

UTIs (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.

Extended Release Tablets

The usual recommended dose is 750 mg twice daily.

For skin and soft tissue infections, streptococcal pharyngitis and mild uncomplicated urinary tract infection the dose is 375 mg twice daily.

Children

Oral Formulations (other than Extended Release Tablets):

The usual recommended daily dosage for children is 25-50 mg/kg 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 - 125 mg 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 75-100mg/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.

Extended Release Tablets:

Children 5 years and over

The usual recommended dose is 375 mg twice daily. The dose may be doubled in severe infections.

Elderly

The dosage is as for adults. The dosage should be reduced if renal function is markedly impaired.

Renal impairment

The dosage should be reduced if renal function is markedly impaired (see *4.4 Special Warnings and Precautions for Use*).

Hepatic impairment

There are no relevant data available.

4.3. Contraindications

Cephalexin is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Severe systemic infections, which require parenteral cephalosporin treatment, should not be treated orally during the acute stage.

4.4. Special Warnings and Precautions for Use

Hypersensitivity reactions

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. If the patient experiences an allergic reaction cephalexin should be discontinued and treatment with the appropriate agents initiated.

Acute generalized exanthematous pustulosis (AGEP)

Acute generalized 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.

Pseudomembranous colitis

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.

Superinfection

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.

Renal impairment

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.

Direct Coombs test

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.

False-positive glycosuria reaction

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.

Azo dye

Some *PHEXIN* formulations (i.e., *PHEXIN CAPSULE, PHEXIN SUSPENSION, PHEXIN DISPERSIBLE KID TABLET, PHEXIN DISPERSIBLE TABLET, PHEXIN PAEDIATRIC DROPS*) may contain azo dye [Sunset Yellow / Tartrazine / Ponceau 4R] (see *List of Excipients* in *Section 2. Qualitative and Quantitative Composition*), which may cause allergic-type reactions.

Aspartame

Some *PHEXIN* formulations *(i.e., PHEXIN REDISYP)* may contain a source of phenylalanine (see *List of Excipients* in *Section 2. Qualitative and Quantitative Composition*).

May be harmful for people with phenylketonuria.

4.5. Drug Interactions

Bacteriostatic antibiotics

As cephalosporins like cephalexin are only active against proliferating microorganisms, they should not be combined with bacteriostatic antibiotics.

Uricosuric drugs

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

Metformin

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

Increased risk of nephrotoxicity

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

Oral anticoagulants

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

Typhoid vaccine

Cephalexin, like other antibiotics with antibacterial activity against salmonella typhi organisms, may interfere with the immunological response to the live typhoid vaccine. The appropriate period of time should elapse between the administration of the last dose of the antibiotic and the live typhoid vaccine.

Oral contraceptives

Cephalexin may reduce the effects of oral contraceptives.

Cytotoxic drugs

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

4.6. Use in Special Populations

Pregnancy

It should be administered with caution during pregnancy.

There is no experimental or clinical evidence of teratogenic effects attributable to cephalexin.

Lactation

Cephalexin is excreted in human milk in low concentrations and should be used with caution in nursing mothers.

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.

4.7. Effects on Ability to Drive and Use Machines

There are no effects on ability to drive or to operate machinery.

4.8. Undesirable Effects

Clinical Trial and Post Marketing Data

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, toxic epidermal necrolysis (exanthematic necrolysis) and acute generalized exanthematous pustulosis (AGEP) (with unknown frequency). These reactions usually subsided upon discontinuation of the drug, although in some cases supportive therapy may be necessary. Anaphylaxis has 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.

4.9. Overdose

Signs and Symptoms

Symptoms of overdosage may include nausea, vomiting, epigastric distress, diarrhoea and haematuria.

Treatment

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 reduced by haemodialysis or by 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.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group**:** First-generation cephalosporins.

ATC Code: J01DB01.

5.1. Mechanism of Action

Cephalexin is an oral broad-spectrum antibiotic. In adequate concentrations it is bactericidal for sensitive proliferating microorganisms by inhibiting the biosynthesis of the cell wall.

5.2. Pharmacodynamic Properties

It is active against the following pathogens:

Gram Positive

Staphylococci (coagulase positive as well as penicillinase-producing strains), *Streptococci, Pneumococci, Corynebacterium diphtheriae, Baccillus anthracis, Clostridia, Listeria monocytogenes, Bacillus subtilis* and *Bacteroides melaninogenicus.*

Gram Negative

Escherichia coli, Salmonellae, Shigellae, Neisseria, Proteus mirabilis, Haemophilus influenzae (some strains), *Brucellae, Klebsiella* species, *Treponema pallidum* and *actinomycetes.*

5.3. Pharmacokinetic Properties

Absorption

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 μg per ml; doubling the dose doubles the peak concentration.

Distribution

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

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.

6. NONCLINICAL PROPERTIES

6.1. Animal Toxicology and Pharmacology

Cephalexin is not anticipated to cause any genotoxic or carcinogenic effects, although no specific studies have been performed to determine this.

7. DESCRIPTION

For details see *Section 2. Qualitative and Quantitative Composition*.

8. PHARMACEUTICAL PARTICULARS

8.1. Incompatibilities

There are no relevant data available.

8.2. Shelf Life

The expiry dates are indicated on the label and packaging.

8.3. Packaging Information

PHEXIN BD TABLETS (Cephalexin Long Acting Tablets 375 mg/ 750 mg)

Blister strips in a carton.

PHEXIN (Cephalexin Capsules IP 250 mg and 500 mg)

PVC/Aluminium blister strips in a carton.

PHEXIN KID TABLETS DISPERSIBLE TABLETS (Cephalexin Tablets IP 125 mg)

Aluminium strips in a carton.

PHEXIN DISPERSIBLE TABLETS (Cephalexin Tablets IP 250 mg)

Aluminium foil strips in a carton.

PHEXIN REDISYP 125 mg / 5 ml and 250 mg / 5 ml (Cephalexin Suspension 125 mg / 5 ml and 250 mg / 5 ml)

Amber PET bottles with a spoon in a carton.

PHEXIN SUSPENSION (For Paediatric Use) (Cephalexin for Oral Suspension IP 250mg/5ml)

HDPE bottles with a measuring cup.

PHEXIN PEDIATRIC DROPS* (*Cephalexin for Oral Suspension IP 100mg/5ml)

HDPE bottle with a dropper in a carton.

All presentations may not be marketed.

8.4. Storage and Handling Instructions

PHEXIN BD TABLET (Cephalexin Long Acting Tablets 375 mg/ 750 mg)

Store protected from moisture, at a temperature not exceeding 25°C.

PHEXIN (Cephalexin Capsules IP 250 mg and 500 mg)

Store protected from moisture, at a temperature not exceeding 30°C.

PHEXIN KID TABLETS DISPERSIBLE TABLETS (Cephalexin Tablets IP 125 mg) / PHEXIN DISPERSIBLE TABLETS (Cephalexin Tablets IP 250 mg)

Store at a temperature not exceeding 30°C protected from light and moisture.
Disperse one tablet in 5 ml (one teaspoonful) of previously boiled and cooled water immediately before use.

PHEXIN REDISYP 125 mg / 5 ml and 250 mg / 5 ml (Cephalexin Suspension 125 mg / 5 ml and 250 mg / 5 ml)

Store in a well closed container at a temperature not exceeding 30°C. Keep protected from direct sunlight. Do not freeze.

Shake vigorously before use.

Do not mix with water.

PHEXIN SUSPENSION (For Paediatric Use) (Cephalexin for Oral Suspension IP 250mg/5ml)

Store at a temperature not exceeding 30°C protected from light and moisture.
Using the measure cup provided, add boiled and cooled water up to the ring mark on the bottle and shake vigorously. Adjust the volume up to the mark by adding more water, if necessary, to make 30 ml i.e. six standard doses.

Prepared suspension to be used within 4 days at room temperature.

Shake well before use.

PHEXIN PEDIATRIC DROPS* (*Cephalexin for Oral Suspension IP 100mg/ml)

Store in a well closed container at temperature not exceeding 30°C. Protect from moisture and direct sunlight.

Keep out of reach of children.

Add boiled and cooled water up to the mark on the label of the bottle or up to the ring mark seen on the bottle (as per the instructions provided on the carton) and shake vigorously.

Adjust the volume up to the mark by adding more water if necessary. This makes 10 ml of the suspension.

The prepared suspension to be stored at room temperature & be used within 4 days.

Shake well before use.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *PHEXIN* formulations. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli
Mumbai 400 030.

11. DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

10-JUN-2025

Version PHE/PI/IN/2025/01

Adapted from Cephalexin NCDS Version 07 dated 3 March 2021.