1.3.1 Summary of Product Characteristic (SmPC)

1.3.1.1 NAME OF THE FINISHED PHARMACEUTICALL PRODUCT

Axcel Cephalexin-250 Capsule

1.3.1.2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients:	Quantity per capsule
Active Ingredient:	
Cephalexin Monohydrate equivalent to Cephalexin	263.0 mg
Excipients:	
Lactose	25.0 mg
Talcum Powder	3.0 mg
Sodium Lauryl Sulphate	7.0 mg
Magnesium Stearate	2.0 mg

1.3.1.3 PHARMACEUTICAL FORM

Capsule. Pink / Ruby red hard gelatin capsule, size 2.

1.3.1.4. CLINICAL PARTICULARS

1.3.1.4.1 Therapeutic indications

Treatment of infections caused by susceptible bacteria:

Respiratory tract infection: acute and chronic bronchitis and infected bronchiectasis. Ear, nose and throat infections: otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis. Urinary tract infections: acute and chronic pyelonephritis, cystitis and prostatitis. Prophylaxis of recurrent urinary tract infection. Gynaecological and obstetric infections.

Skin, soft-tissue and bone infections. Gonorrhoea (when Penicillin is not suitable). Dental procedures: treatment of dental infections. As prophylaxis treatment for patients with heart disease undergoing dental treatment as an alternative to penicillin.

1.3.1.4.2 Posology and method of administration

For oral administration only.

Adult:

Many infections in adult will respond to oral dosage of 1 gram to 2 grams per day in divided dose; however, for most infections, the following simple scheme will be found satisfactory:

Adult and children over 12 years: 500 mg three times daily

To aid compliance, especially in ambulatory patients, the daily dosage may be given two equal doses, e.g. 1g twice daily in adults with the urinary tract infections.

For severe or deep-seated infections, especially when less sensitive organisms are involved, the dosage should be increased to 1g three times daily or 1.5 g four times daily.

Children:

Normal recommended dose for children: 25-60 mg/kg/day.

For chronic, severe or deep-seated infections, this should be increased to 100 mg/kg/day (maximum 4 g/day)

0 to 1 year	: 25-60 mg/kg/day
1 to 2 years	: 62.5 to 125 mg four times daily or 125 to 250 mg twice daily
3 to 6 years	: 125 to 250 mg four times daily or 250 to 500 mg twice daily
7 to 12 years	: 250 to 500 mg four times daily or 500 mg to 1g twice daily

It is recommended to take Axcel Cephalexin-125 Suspension for dosage below 250 mg.

Duration of treatment:

For most acute infections, treatment should continue for at least two days after signs have returned to normal and symptoms have subsided, but in chronic, recurrent or complicated urinary infections, treatment for two weeks (giving 500 mg four times daily) is recommended.

The standard recommended dosage should be halved for patients with severe renal impairment (creatinine clearance < 10 ml/min). The maximum recommended dosages (i.e. adult 6 g/day, children 4 g/day) should be reduced by 50% in mild, 75% in moderate and 87.5% in severe renal failure. Adult patients receiving intermittent dialysis should be given an additional 500 mg cephalexin after each dialysis, i.e. total dosage up to 1 g on that day. Children should receive an additional 8 mg per kg.

1.3.1.4.3 Method of administration

Refer 4.2. Posology and method of administration.

1.3.1.4.4 Contraindications

Contraindicated in patient hypersensitive to cephalosporin.

1.3.1.4.5 Special warnings and precautions for use

Cephalexin should be used with caution for patient with penicillin sensitivity. False positive urinary glucose and false positive Combs' test have been found during the treatment of Cephalexin. Patients with renal impairment should be given with caution.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cephalexin, and may range from mild to life threatening. Therefore, it is important to consider this diagnosis in patients with diarrhea subsequent to the administration of cephalexin. 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.

1.3.1.4.6 Paediatric population (warnings and precautions warnings and precautions)

Not applicable.

1.3.1.4.7 Interaction with other medicinal products and other forms of interaction

Cephalexin decreases the efficacy of oestrogen containing oral contraceptives. The concomitant use of probenecid will reduce the excretion of cephalexin; nephrotoxic drug such as aminoglycoside antibiotic-gentamicin may increase the risk of kidney damage with cephalexin. Concomitant use with loop diuretic-frusemide may enhance nephrotoxicity.

1.3.1.4.8 Additional information on special populations

Not applicable

1.3.1.4.9 Paediatric population (indications)

Not applicable

1.3.1.4.10 Fertility, pregnancy and lactation

Cephalexin is widely distributed in the body. It crosses the placenta and small quantities are found in the milk of nursing mother. Caution should be taken while given to pregnant women and nursing mothers.

1.3.1.4.11 Effects on ability to drive and use machines

None stated

1.3.1.4.12 Undesirable effects

The most common side effects of cephalexin are generally gastro-intestinal disturbances and hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness and anaphylaxis.

1.3.1.4.13 Overdose

There is no effect would be expected due to overdosage. Overdosage has not been reported as a problem when cephalexin is given by mouth. It can be removed by haemodialysis and peritoneal dialysis.

1.3.1.5 PHARMACOLOGICAL PROPERTIES

1.3.1.5.1 Pharmacodynamic properties

Cephalexin is a broad spectrum bactericidal antibiotic. It acts by inhibiting bacterial cell wall synthesis. Cephalexin is active against the following organisms *in vitro.* Beta-haemolytic Streptococci, *Staphylococci,* including coagulase-positive, coagulase-negative and penicillinase-producing strains, *Streptococcus pneumonia, Escherichia coli, Proteus mirabilis, Klebsiella sp, Haemophilius infuenzae, Neisseria catarrhalis*. Most strains of *enterococci (Streptoccocus faecalis)* and few strains of staphylococci resistant to cephalexin. It is no active against most strains of *Enterobacter species, P.morganii, and P.vulgaris*. It has no activity against *Pseudomonas* or *Herellae species*. When tested *by in vitro* methods, Staphylococci exhibit cross- resistance between cephalexin and penicillin-type antibiotic.

1.3.1.5.2 Pharmacokinetic properties

Cephalexin is almost completely absorbed from the gastro-intestinal tract. If cephalexin is taken with food, absorption may be delayed, but the total amount absorbed is not appreciably altered. It is widely distributed in the body but does not enter the cerebrospinal fluids in significant quantities. It is not metabolised. About 80% or more of a dose is excreted unchanged in the urine

1.3.1.5.3 Preclinical safety data

Not applicable

1.3.1.6 PHARMACEUTICAL PARTICULARS

1.3.1.6.1 List of excipients

1. Lactose
2. Talcum Powder
3. Sodium Lauryl Sulphate
4. Magnesium Stearate

1.3.1.6.2 Incompatibilities

Not stated.

1.3.1.6.3 Shelf life

3 years

1.3.1.6.4 Special precautions for storage

Keep container well closed. Store below 30°C. Protect from light.

1.3.1.6.5 Nature and contents of container

Available in Blister pack of 10 x 10's.
Material: Polyvinyl chloride blister film
Closure and liner: Aluminium foil

1.3.1.6.6 Special precautions for disposal and other handling

Not applicable.

1.3.1.7 MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Kotra Pharma (M) Sdn. Bhd.
1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

1.3.1.8 MARKETING AUTHORISATION NUMBER

Malaysia: MAL20014216AZ

1.3.1.9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

25 October 2001

1.3.1.10 DATE OF REVISION OF THE TEXT

13 August 2018