SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Cefuroxime for Injection USP 750 mg (CEFURONET 750)

2. Qualitative and quantitative composition
Each combipack contains:
A: One vial of:
Cefuroxime Sodium (Sterile) USP
Eq. to Cefuroxime 750 mg
B: One ampoule of:
Sterile Water for Injection BP 10 ml

3. Pharmaceutical form
Dry powder for Injection.
White powder.

4. Clinical particulars
4.1 Therapeutic indications
CEFURONET is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.
It is indicated for the treatment of infections before the infecting organism has been identified or when caused by sensitive bacteria. Susceptibility to CEFURONET will vary with geography and time and local susceptibility data should be consulted where available.
Indications include:
– respiratory tract infections for example, acute exacerbation of chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections
– ear, nose and throat infections for example, sinusitis, tonsillitis, pharyngitis and otitis media
– urinary tract infections for example, acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria
– soft-tissue infections for example, cellulitis, erysipelas and wound infections
– bone and joint infections for example, osteomyelitis and septic arthritis
– obstetric and gynaecological infections, pelvic inflammatory diseases
– gonorrhoea particularly when penicillin is unsuitable
– other infections including septicaemia, meningitis and peritonitis
– prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.
Usually CEFURONET will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole (orally or by suppository or injection), especially for prophylaxis in colonic or gynaecological surgery.
Where appropriate CEFURONET is effective when used prior to oral therapy with CEFURONET TABLET in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

4.2 Posology and method of administration
General dosing recommendations
Adults
Many infections respond to 750 mg three times daily by i.m. or i.v. injection. For more severe infections the dose should be increased to 1.5 g three times daily given i.v. The frequency of administration may be increased to 6-hourly if necessary, giving total daily doses of 3 to 6 g. Where clinically indicated, some infections respond to 750 mg or 1.5 g twice daily (i.v. or i.m.) followed by oral therapy with CEFURONET TABLET.

Infants and Children

30 to 100 mg/kg/day given as 3 or 4 divided doses. A dose of 60 mg/kg/day is appropriate for most infections.

Neonates
30 to 100 mg/kg/day given as 2 or 3 divided doses (see Pharmacokinetics).

Gonorrhoea
Adults
1.5 g as a single dose (as 2 x 750 mg injections given i.m. with different sites e.g. each buttock).

Meningitis
CEFURONET is suitable for sole therapy of bacterial meningitis due to sensitive strains.
Adults: - 3 g given i.v. every 8 hours.
Infants and Children: - 150 to 250 mg/kg/day given i.v. in 3 or 4 divided doses
Neonates: - the dosage should be 100 mg/kg/day given i.v.

Prophylaxis
The usual dose is 1.5 g given i.v. with induction of anaesthesia for abdominal, pelvic and orthopaedic operations. This may be supplemented with two 750 mg i.m. doses 8 and
16 hours later.
In cardiac, pulmonary, oesophageal and vascular operations, the usual dose is 1.5 g given
i.v. with induction of anaesthesia, continuing with 750 mg given i.m. three times daily for a further 24 to 48 hours.
In total joint replacement, 1.5 g CEFURONET powder may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer.

Sequential therapy
Adults
Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

Pneumonia
1.5 g CEFURONET three times daily or twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily CEFURONET TABLET oral therapy for 7 to10 days.

Acute exacerbations of chronic bronchitis
750 mg CEFURONET three times daily or twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily CEFURONET TABLET oral therapy for 5 to10 days.

Renal impairment
Cefuroxime is excreted by the kidneys. Therefore, as with all such antibiotics, in patients with markedly impaired renal function it is recommended that the dosage of CEFURONET should be reduced to compensate for its slower excretion.
It is not necessary to reduce the standard dose (750 mg to 1.5 g three times daily) until the creatinine clearance falls to 20 ml/min or below.
In adults with marked impairment (creatinine clearance 10 to 20 ml/min) 750 mg twice daily is recommended and with severe impairment (creatinine clearance <10 ml/min) 750 mg once daily is adequate.
For patients on haemodialysis a further 750 mg dose should be given i.v. or i.m. at the end of each dialysis. In addition to parenteral use, CEFURONET can be incorporated into the peritoneal dialysis fluid (usually 250 mg for every 2 litres of dialysis fluid).
For patients in renal failure on continuous arteriovenous haemodialysis or high-flux haemofiltration in intensive therapy units a suitable dosage is 750 mg twice daily. For low-flux haemofiltration follow the dosage recommended under impaired renal function.

4.3 Contraindications

Hypersensitivity to cephalosporin antibiotics.

4.4 Special warnings and precautions for use

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams.

Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with potent diuretics such as furosemide or aminoglycosides, as renal impairment has been reported with these combinations. Renal function should be monitored in these patients, the elderly, and those with pre-existing renal impairment (see Dosage and Administration).

As with other therapeutic regimens used in the treatment of meningitis, mild-to-moderate hearing loss has been reported in a few paediatric patients treated with CEFURONET. Persistence of positive cerebral spinal fluid (CSF) cultures of Haemophilus influenzae at 18-36 hours has also been noted with CEFURONET injection, as well as with other antibiotic therapies; however, the clinical relevance of this is unknown.

As with other antibiotics, use of CEFURONET may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of other non-susceptible organisms (e.g. enterococci and Clostridioides difficile), which may require interruption of treatment.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Intracameral use and ocular toxicity

Serious ocular toxicity, including corneal opacity, retinal toxicity and visual impairment has been reported following off-label intracameral use of CEFURONET. CEFURONET should not be administered intracamerally.

With a sequential therapy regime, the timing of change to oral therapy is determined by severity of the infection, clinical status of the patient and susceptibility of the pathogens involved. If there is no clinical improvement within 72 hours, then the parenteral course of treatment must be continued.

Refer to the relevant prescribing information for CEFURONET TABLET before initiating sequential therapy.

4.5 Interaction with other medicinal products and other forms of interaction

In common with other antibiotics, CEFURONET may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

CEFURONET does not interfere in enzyme-based tests for glycosuria.

Slight interference with copper reduction methods (Benedict's, Fehling's, Clinitest) may be observed. However, this should not lead to false-positive results, as may be experienced with some other cephalosporins. It is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving CEFURONET.

This antibiotic does not interfere in the alkaline picrate assay for creatinine.

4.6 Fertility, pregnancy and lactation

There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime, but, as with all drugs, it should be administered with caution during the early months of pregnancy. Cefuroxime is excreted in human milk, and consequently caution should be exercised when CEFURONET is administered to a nursing mother.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, based on known adverse reactions, cefuroxime is unlikely to have an effect on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions are very rare (<1/10,000) and are generally mild and transient in nature.
The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data for calculating incidence are not available. In addition, the incidence of adverse reactions associated with CEFURONET may vary according to the indication.
Data from clinical trials were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.
The following convention has been used for the classification of frequency:

Very common	≥1/10,
Common	≥1/100 to <1/10,
Uncommon	≥1/1000 to <1/100,
Rare	≥1/10,000 to <1/1000,
Very rare	<1/10,000.

Infections and infestations
Rare Candida overgrowth

Blood and lymphatic system disorders

Common	Neutropenia, eosinophilia.
Uncommon	Leukopenia, decreased haemoglobin concentration**,** positive Coomb's test.
Rare	Thrombocytopenia.
Very rare	Haemolytic anaemia.

Cephalosporins as a class tend to be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug to produce a positive Coomb's Test (which can interfere with cross matching of blood) and very rarely haemolytic anaemia.

Immune system disorders
Hypersensitivity reactions including

Uncommon	Skin rash, urticaria and pruritus**.** Rare Drug fever.
Very rare	Interstitial nephritis, anaphylaxis, cutaneous vasculitis. See also Skin and subcutaneous tissue disorders and Renal and urinary disorders.

Gastrointestinal disorders

Uncommon	Gastrointestinal disturbance.
Very rare	Pseudomembranous colitis (*see Warnings and Precautions*).

Hepatobiliary disorders

Common	Transient rise in liver enzymes.
Uncommon	Transient rise in bilirubin.

Transient rises in serum liver enzymes or bilirubin occur, particularly in patients with pre- existing liver disease, but there is no evidence of harm to the liver.

Skin and subcutaneous tissue disorders

Very rare	Erythema multiforme, toxic epidermal necrolysis and Stevens Johnson Syndrome. See also Immune system disorders.

Renal and urinary disorders

Very rare	Elevations in serum creatinine, elevations in blood urea nitrogen and decreased creatinine clearance (*see Warnings and Precautions).* See also Immune system disorders.

General disorders and administration site conditions

Common Injection site reactions which may include pain and thrombophlebitis.
Pain at the intramuscular injection site is more likely at higher doses. However, it is unlikely to be a cause for discontinuation of treatment.

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

4.9 Overdose
Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis or peritoneal dialysis.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Therapeutic Classification (ATC Code): J01DC02
Cefuroxime is a well characterized and effective antibacterial agent which has bactericidal activity against a wide range of common pathogens, including β-lactamase producing strains. Cefuroxime has good stability to bacterial β-lactamase, and consequently is active against many ampicillin-resistant or amoxycillin-resistant strains.
The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.
The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

5.2 Pharmacokinetic properties
Peak levels of cefuroxime are achieved within 30 to 45 minutes after i.m. administration.
Protein binding has been variously stated as 33 - 50% depending on the methodology used.
Concentrations of cefuroxime in excess of the minimum inhibitory levels for common pathogens can be achieved in bone, synovial fluid and aqueous humour. Cefuroxime passes the blood-brain barrier when the meninges are inflamed.
Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion.
The serum half-life after either i.m. or i.v. injection is approximately 70 minutes.
In the first weeks of life the serum half-life of cefuroxime can be 3 to 5 times that in the adult.
Concurrent administration of probenecid prolongs the excretion of the antibiotic and produces an elevated peak serum level.
There is an almost complete recovery (85 to 90%) of unchanged cefuroxime in urine within 24 hours of administration. The major part is excreted in the first 6 hours.
Serum levels of cefuroxime are reduced by dialysis.

5.3 Preclinical Safety Data
Subcutaneous administration of cefuroxime to mice at a dose of 4 g / kg had no significant effect on the central nervous system, on spontaneous locomotor activity or motor co-ordination and no anticonvulsant, analgesic, tranquilizing or antidepressant properties. Doses of up to and including 300 mg / kg cefuroxime given intravenously to cats and dogs produced no pharmacodynamic effects on the cardiovascular or respiratory systems other than small variations in blood pressure and heart rate in the cat, which were not dose-related. However, doses of 1 and 3 g / kg produced an initial transitory tachycardia, a decrease in blood pressure followed by bradycardia and an increase in blood pressure. In neither species did cefuroxime affect the responses of the cardiovascular system to intravenously-injected neurohumoral agents. Ganglionic transmission was not affected in the cat.

Cefuroxime had no effect on isolated smooth muscle preparations at a concentration in the bathing fluid of 10-5M. Only minor increases in contractile force and rate of contraction of the isolated rabbit heart (Langendorff preparation) were observed when the concentration in the perfusing fluid was increased to 10-2M. A 30% solution of cefuroxime in 0.9% saline had no local anaesthetic activity nor any irritant effect to the cornea of the rabbit eye.
Cefuroxime had no significant effect on the cortical EEG of rats.

6. Pharmaceutical particulars
6.1 List of excipients
None

6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section 4.2.

6.3 Shelf life
Product as packaged for sale: 30 Months
The expiry date of the powder is indicated on the packaging.
The unopened pack storage temperature requirements are indicated on the packaging. If unopened product previously stored below 30ºC.

Shelf life after reconstitution and dilution under controlled and validated aseptic conditions:
suspension and solution for Injection - 5 hours below 25ºC or 72 hours at 2 to 8ºC Solution for Infusion - 3 hours below 25ºC or 72 hours at 2 to 8ºC

Shelf life if reconstitution and dilution has not taken place in controlled and validated aseptic conditions:
The product should be used immediately or within 24 hours if stored at 2 to 8oC. If unopened product previously stored below 30ºC

6.4 Special precautions for storage
Store below 30ºC in a cool and dry place. Protect from light and moisture.
Following reconstitution: 2°C-8°C

6.5 Nature and contents of container
10 ml glass vial with grey bromo butyl rubber stopper and 20 mm flip off seal, such one vial and one 10 ml WFI is packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Galaxy Pharmaceutical Ltd.
PO Box 39107-00623, Nairobi, Kenya.

Manufacturer
Saitech Medicare Pvt. Ltd.
Trilokpur road, Kala-Amb
Dist. Sirmor, Himachal Pradesh (INDIA).

8. Marketing Authorization Number
CTD12749

9. Date of first <registration> / renewal of the <registration>
01/06/2026

10. Date of revision of the text
01/06/2026