Fenemor™ 200

Faropenem Sodium 200 mg Tablet

Oral Penem with Proven Efficacy

Product Description:

Fenemor 200: Each film coated tablet contains Faropenem sodium 200 mg

General Information

Faropenem is an orally-active beta-lactam antibiotic belonging to the penem group.

Faropenem is a penem with a tetrahydrofuran substituent at position C2, with broad-spectrum antibacterial activity against many gram-positive and gram-negative aerobes and anaerobes. Compared with imipenem, faropenem has improved chemical stability and reduced central nervous system effects. In addition, faropenem is resistant to hydrolysis by many beta-lactamases.

Microbiology:

Faropenem was found to be active against Enterococcus faecalis, oxacillinsusceptibleStaphylococci, Neisseria gonorrhoeae, Neisseria meningitides,Haemophillus influenzae, Moraxella catarrhalis, Streptococcus pyogenes,Staphylococcus saprophyticus, Staphylococcus epidermidis, Group AStreptococci, Group B Streptococci, Streptococcus milleri, Streptococcusviridans, Staphylococcus aureus, Enterococcus faecalis, Enterococcus faecium,E. coli, Klebsiella spp., Proteus mirabilis, Citrobacter spp., Salmonella spp.,Shigella spp., Providentiastuartii, Bacteroides fragilis, Clostridium perfringens,andPeptostreptococcusspp

Indication & Usage:

Fenemor 200 Tablets are indicated in the treatment of the following infections:

- **Urinary tract infections**: Eg, pyelonephritis, cystitis, prostatitis, seminal gland inflammation.
- **Lower respiratory tract infections**: Eg, acute bronchitis, pneumonia,pulmonary suppuration.

- **Ear, nose and throat (ENT) infections:**Eg, otitis externa, tympanitis, sinusitis
- **Upper respiratory tract infections:**Eg, pharyngitis, tonsillitis.
- **Skin and skin structure infections:**Eg, pustular acne, folliculitis, contagious impetigo, erysipelas, lymphangitis, suppurative nail inflammation, subcutaneousabscess, hidradenitis (sweat gland inflammation), infective sebaceous cyst,chronic pyoderma, secondary infection of external wounds or surgical wound.

DOSAGE AND ADMINISTRATION:

Indication	Dosage
Urinary tract infections	200 mg t.i.d., can be increased to 300mg t.i.d.
Lower respiratory tract infections	200 mg t.i.d., can be increased to 300mg t.i.d.
Upper respiratory tract infections	150 mg t.i.d., can be increased to 200mg t.i.d.
Skin and skin structure infections	150 mg t.i.d., can be increased to 200mg t.i.d.
ENT infections	200 mg t.i.d., can be increased to 300mg t.i.d.

Duration of treatment: The duration of treatment depends upon the severity of infection, clinical response and bacteriological findings.

Mechanism of action:

Like other beta-lactam antibiotics, faropenem acts by inhibiting the synthesis of bacterial cell walls. It inhibits cross-linkage between the linear peptidoglycan polymer chains that make up a major component of the cell wall of Gram-positive bacteria. It does this by binding to and competitively inhibiting the transpeptidase enzyme used by bacteria to cross-link the peptide (D-alanyl-alanine) used in peptidogylcan synthesis.

Pharmacokinetic:

Absorption: After a single oral dose of faropenem in fasting healthy volunteers at 150, 300, and 600 mg, the plasma levels of faropenem reached $C_{max}$of 2.4, 6.2, and 7.4 mg/ml, respectively, at about 1–1.5 hours (T_{max}). The AUCs of faropenem were3.94, 11.73, and 19.59 µg.h/ml. These $C_{max}$and AUCs were proportional to thedoses, and the respective urinary recoveries were 3.12%, 6.78%, and 5.26% ofthe dose. The half-life of faropenem is about 1 hour, irrespective of the dosagequantity.
At a single dose of 300 mg in normal healthy adults after meals, the average $T_{max}$was delayed by about 1 hour, but C_{max}, AUC and urinary recovery were notdifferent from those in the fasting state. In a multiple dose study with 400 mgt.i.d., the C_{max}on days 1, 4, and 7 (1^{st}, 10^{th} and 19^{th} administration)

were 5.5, 4.3,and 4.8 mg/ml, respectively. The respective AUCs were 12.5, 10.1, and 12.2mg.h/ml, demonstrating no cumulative effect.

Distribution: Faropenem was found in the sputum of patients, fluid that oozes at the time oftooth extraction, tonsil tissues, maxillary sinus, mucous membrane tissues,female genital organ tissues, eyelids, subcutaneous cell tissues and prostatetissues.

Metabolism& Excretion:

Before excretion in the urine, the absorbed faropenem gets metabolized bydehydropeptidase-I (DHP I), which is present in the kidneys. The metabolites arefound in the blood and the urine. The metabolites do not demonstrateantibacterial activity. Faropenem is primarily excreted through the kidneys andthe rate of excretion in the urine (0 ~ 24 hours) of 150, 300, and 600 mg (givenon an empty stomach to normal healthy adults) was 3.1 ~ 6.8%. The highestconcentration in the urine was 21.7, 55.6, and 151.5 mg/ml, respectively, in 0–2hours; after 12 hours, it was almost reduced to nil.

Use in Specific Population:

Pregnancy: Safety regarding therapy during pregnancy has not been established. In pregnant women or expectant mothers, the medicine should be given only if the benefits of the treatment are greater than the risks involved.

Nursing Mother: Faropenem is excreted in human milk. Therefore, Faropenem should be given to nursing mothers only if the benefits outweigh the risks.

Pediatric Use: Safety regarding therapy in infants has not been established.

Geriatic Use: The half-life of faropenem is prolonged in the elderly and this may be due to a decline in kidney functions, which results in high plasma concentrations.
Therefore, in the elderly, start with a dose of 150 mg and monitor the patient for
any undesirable effects.
If diarrhea and loose bowel movements appear, stop the medicine, monitorcorrectly and take appropriate measures. There is a tendency of hemorrhage dueto vitamin K deficiency in the elderly.
Contraindication: Faropenem is contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class, or in patients who have demonstrated anaphylactic reactions to beta-lactams.

Warning & Precaution:

Faropenem should be administered with caution in the following:

1. Patients with a past history of hypersensitivity to penicillin, cephem orcarbapenem drugs.
2. Patients with a family history of atopy.
3. Patients with renal impairment. The dosage should be reduced or theinterval between doses should be increased.
4. Geriatric patients.

5. Patients with poor oral intake or poor general state (since there are cases that show symptoms of vitamin K deficiency, proper monitoring should bedone).

Drug Interaction:

- **Imipenem and Cilastatin sodium combination:** It has been reported that in animal studies (rat), the concentration of faropenem in the blood increases. It is due to the obstruction of metabolic fermentation by cilastatin.
- **Furosemide:** It has been reported in animal studies (dog), that the kidney toxicity of faropenem increases.
- **Sodium valproate:** It has been reported that due to joint usage with carbapenem drugs (meropenem, panipenem and imipenem-cilastatin sodium) the concentration of valproic acid in the blood reduces, and there is a recurrence of epileptic fits.

Adverse Reactions:

Faropenem is generally well tolerated. The most frequently reported adverse reactions are diarrhea, abdominal pain, loose bowel movements, nausea and rash.