Leaflet Enoxabid 400mg
Size: 120 x 150mm
Date: 28-08-2015
Ammara Commercial Printers (Pvt.) Ltd.

Enoxabid (Enoxacin Sesquihydrate) 400mg Tablets

Description
Enoxabid is Abbott's brand name for Enoxacin, a new broad spectrum antibacterial agent of the quinolone class.

Composition
Each Film tab tablet contains:
Enoxacin sesquihydrate equivalent to Enoxacin ---- 400 mg

Clinical Pharmacology
Enoxacin blocks DNA synthesis during bacterial replication by inhibiting the bacterial enzyme DNA gyrase.
It has a broad antibacterial spectrum against Gram-positive and Gram-negative bacteria at bioavailable concentrations achievable in body tissues and fluids.
In vitro, it is usually bactericidal at concentrations near its MICs and showing high antibacterial activity against Staphylococcus aureus, Staphylococcus epidermidis and Streptococcus pyogenes as well as Campylobacter spp, Clostridium spp, Enterobacter spp, Escherichia coli, Klebsiella spp, Proteus spp, Providencia spp., Pseudomonas aeruginosa, Pseudomonas cepacia, Pseudomonas maltophilia, Serratia spp, Shigella spp, Salmonella spp, Vibrio spp, Haemophilus influenzae, Haemophilus ducreyi, Neisseria gonorrhoeae, Legionella spp, and strains of Acinetobacter spp.
However, streptococci are less sensitive or resistant to it.
Penicillin, methicillin and/or amoxicillin-resistant isolates of other bacteria are susceptible to Enoxacin.
Enoxacin does not exhibit any significant cross-resistance with other antibacterial agents and has a low frequency of spontaneous resistant mutants. At subinhibitory concentrations in vitro, it has been shown to lower the incidence of plasmid transfer and to cause plasmid elimination (plasmid curing effect).
It acts synergistically with polymorphonuclear leukocytes to enhance bactericidal killing of bacteria.
Oral Enoxacin showed protective activity against Gram-positive and Gram-negative infections in systemic circulation and organ systems (i.e. lung, skin, bowel) of experimental mice. In rabbits when administered orally, it did not significantly suppress the anaerobic/streptococcal flora.
Pharmacological evaluations of Enoxacin in animals and isolated organs suggests that its preclinical potential for CNS and autonomous side effects is small, especially with oral administration.
Orally administered Enoxacin is rapidly and reliably absorbed.
After a single dose of 400 mg, peak serum levels of 2-3 mcg/ml occur at 1.5 hours on average. Meals have no significant influence on the rate and extent of absorption.
On multiple doses, steady state concentrations are reached within 3 days, e.g., 3.5 - 4.5 mcg/ml peaks with a 400 mg twice daily schedule. The serum half-life is about 5-6 hours with plasma levels remaining above the minimal inhibitory concentrations for susceptible clinical pathogens.
Enoxacin diffuses readily into most body fluids and tissues except the cerebrospinal fluid and is eliminated by both the renal and hepatic routes.
It is predominantly excreted via the kidney with 24 hour urinary recovery of about 60-65% and steady-state urine concentrations 10-100 times higher than the plasma levels. It is concentrated in the bile to mean levels up to 9 times higher than plasma levels. It penetrates sputum, skin blister fluid, prostate and renal tissues to levels in most cases exceeding that of plasma and into middle ear fluid, tonsillar and maxillary sinus tissues at concentrations similar to corresponding plasma levels.
Enoxacin is metabolized to a very limited extent, its bioactivation occurring primarily in the presence of a ring to form mainly on oxometabolite (with 1/10th the microbiological activity of the parent compound) and 6 other minor metabolites. 38 - 44%, and at least 90% of unchanged Enoxacin are recovered, respectively, in the urine and feces, the metabolites accounting for the urine in 11-12% and each of the other metabolites for less than 3% of the administered dose.
In severe renal impairment, i.e., with a creatinine clearance lower than 30 ml/minute, the elimination half-life is approximately doubled. This change in elimination kinetics should double the steady-state plasma concentrations.

INDICATIONS
Enoxabid is indicated in the following infections caused by susceptible organisms:
Upper Respiratory Tract Infections: Pharyngitis, tonsillar abscess, otitis media, sinusitis.
Lower Respiratory Tract: Acute bronchitis, acute exacerbations of chronic bronchitis, bronchopneumonia, infections, pneumonia and lung abscesses.
Skin/Skin Structures: Folliculitis, furunculosis, carbuncles, impetigo, cellulitis, secondary infections of wounds, burns and surgical incisions.
Urinary Tract: Acute simple and chronic complicated urinary tract infections, including cystitis, pyelonephritis and prostatitis.
Sexually Transmitted Diseases: Gonococcal urethritis.
GI Tract: Bacillary dysentery and enteritis, Typhoid (enteric fever).

CONTRAINDICATIONS
Enoxabid is contraindicated in patients who have known hypersensitivity to the antimicrobial agent or other quinolones.

PRECAUTIONS
Enoxabid should be carefully administered to patients with:
- Severe renal dysfunction or undergoing hemodialysis.
- A known history of epilepsy or other convulsive disorder as convulsions may occur. (Patients must be closely monitored).

USAGE IN PREGNANT AND NURSING MOTHERS AND IN CHILDREN
- Safe use of Enoxabid during pregnancy and nursing has not been established. Therefore, it should not be administered to
Orally administered Enoxacin is rapidly and reliably absorbed.

autonomous side effects is small, especially with oral

Pharmacological evaluations of Enoxacin in animals and isolated

anaerobic/streptococcal flora.

Oral Enoxacin showed protective activity against Gram-positive

It acts synergistically with polymorphonuclear leukocytes to

mutants. At subinhibitory concentrations in vitro, it has been

Enoxacin does not exhibit any significant cross-resistance with

other bacteria are as susceptible as the sensitive strains.

Enoxacin sesquihydrate equivalent to Enoxacin .......... 400 mg.

spectrum antibacterial agent of the quinolone class.

- A known history of epilepsy or other convulsive disorder as

- Hypersensitivity to this antimicrobial agent or other quinolones.

Enoxacin is contraindicated in patients who have known

GI Tract:

Bacillary dysentery and enteritis, Typhoid (enteric

Sexually Transmitted Diseases:

Urinary Tract:

surgical incisions.

Skin/Skin Structures:

and lung abscess.

Upper Respiratory Tract / ENT:

Otitis media, sinusitis.

Concurrent administration of antacids containing magnesium

ry analgesics of the phenylacetic acid or propionic acid group (e.g.

Concurrent use of Enoxacin with theophylline has been reported

to enhance the effects of theophylline by elevating its serum

level.

Since Lyell syndrome and Stevens Johnson syndrome may

occur rarely, the patient should be monitored carefully.

Administration of Enoxacin must be discontinued when any

abnormality is observed and the patient should be treated

appropriately.

Muscular: Rhabdomyolysis occurring with acute renal function

disorder, characterized by myalgia, weakness, elevation of CK,

and elevation of plasma myoglobin level, may occur.

Therefore, appropriate precautions should be taken.

Skin: Since Lyell syndrome and Stevens Johnson syndrome may

occur rarely, the patient should be monitored carefully.

Administration of Enoxacin must be discontinued when any

abnormality is observed and the patient should be treated

appropriately.

Other: Palpitation, precordial discomfort, tachycardia, hypoglycemic

symptoms, diminished taste or backache may rarely occur.

DOSAGE AND ADMINISTRATION

For the treatment of acute and chronic infections, the usual daily

dosage is 400 mg to 800 mg in two divided doses

for up to 7-14 days or longer, depending on the severity response

of the infection.

For the treatment of typhoid fever 400 mg, twice daily for 10-14

days.

For the treatment of gonococcal urethritis, the recommended

dosage is 400 mg as a single dose. In patients with severe

impairment of renal function, the dosage must be adjusted either

by dividing the normally recommended dose by two or by

multiplying the interval between doses (in hours) by two.

Storage: Protect from excessive heat, light & moisture.

How Supplied: Enoxacin 400 mg. Film-Coated Tablets packed in

blister strips of 2x10s in a carton. List No. F 698

Manufactured by:

Abbott Laboratories (Pakistan) Ltd.

Landhi, Karachi.

01-078R3