**Enoxabid 400mg Tablets**

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

**Composition**
Each Filmtablet 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.

**Oral Administration**
Orally administered Enoxacin is rapidly and reliably absorbed. Autonomic side effects are small, especially with oral administration. Convulsions may occur (patients must be closely monitored). The administration should be discontinued when such symptoms are observed.

**DRUG INTERACTION**
Concurrent administration of antacids containing magnesium should be avoided. Concurrent use of Enoxacin with non-steroidal anti-inflammatory drugs of the phenylacetic acid or propionic acid group (e.g., fenbufen) and, therefore, co-administration should be done with caution. Concurrent administration of antacids containing magnesium can enhance the effects of theophylline by elevating its serum and plasma levels.

**CONTRAINdications**
Enoxacin is contraindicated in patients who have known hypersensitivity to the antimicrobial agent or other quinolones.

**PRECAUTIONS**
Enoxacin should be administered to patients with:
- Severe renal dysfuncion or undergoing hemodialysis. This drug is only removed slightly by 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 pregnant and nursing women suspected of being pregnant, pregnant or nursing.

**Pharmacokinetics**

- Enoxacin is distributed in concentration ranging from 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.

**Pharmacodynamics**
Enoxacin is metabolized to a very limited extent, its biotransformation occurring primarily in the piperazinyl ring to form mainly on oxosan inosine with the microsomal activity of the parent compound.

**Pharmacology**
Enoxacin does not exhibit any significant cross-resistance with other antimicrobial agents. It is effective against a wide range of Gram-positive and Gram-negative bacteria.

**Pharmacology of Renal Impairment**
In severe renal impairment, i.e., with a creatinine clearance lower than 0.1% of the patients’ normal value, the dose should be reduced and more frequent drug monitoring should be carried out.

**List of Indications**
- Acute and chronic infections, the usual daily dosage is 400 mg as a single dose. In patients with severe infections, the recommended dosage is 400 mg twice daily for 10-14 days.
- For the treatment of gonococcal urethritis, the recommended dosage is 400 mg twice daily for 7-14 days.
- For the treatment of typhoid fever, the recommended dosage is 400 mg twice daily for 10-14 days.
- For the treatment of upper respiratory tract infections, including the common cold, bronchitis, and sinusitis, the recommended dosage is 400 mg twice daily.
- For the treatment of acute bronchitis, the recommended dosage is 400 mg twice daily for 10-14 days.

**Pharmacology of Absorption**
Enoxacin is well absorbed after oral administration. Absorption is not significantly affected by food. Absorption is rapid and reaches peak plasma concentrations within 1-2 hours. Absorption is complete and recovery of about 60-65% and steady-state urine concentrations are reached in a few days.

**Pharmacology of Distribution**
Enoxacin is widely distributed in body tissues and fluids. The plasma 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.

**Pharmacology of Elimination**
Enoxacin is excreted via the kidneys with 24-hour urinary recovery of about 60-65% and steady-state urine concentrations are reached in a few days. The plasma 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.

**Pharmacology of Metabolism**
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**Usage in Elderly Patients**
In elderly patients, decreased renal function is frequently observed. Higher serum levels may be maintained in these cases and adverse reactions tend to develop. The drug should therefore be administered carefully paying attention to dosage and intervals of administration.

**Warnings and Precautions**

**Peripheral Neuropathy:** Cases of sensory or sensorimotor axon polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesia, dysesthesias and weakness have been reported in patients receiving fluoroquinolones.

**Vision Disorders:** The association between fluoroquinolone intake and occurrence of retinal detachment has been investigated in several epidemiological studies using various designs and data sources. Studies have found a statistically significant increased risk. Therefore, small increase in risk cannot be excluded, especially in patients with risk factors. If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.

**Drug Interaction**
Concurrent use of Enoxacin with theophylline has been reported to enhance the effects of theophylline by elevating its serum level. Therefore, the dosage of theophylline should be reduced during concurrent therapy.

There is a possibility of convulsive episodes caused by the concomitant use of Enoxacin with non-steroidal anti-inflammatory agents of the phenylacetic acid or propionic acid group (e.g., fenbufen) and, therefore, co-administration should be done carefully.

Concurrent administration of drugs containing magnesium hydroxide or aluminium hydroxide may interfere with the absorption of Enoxacin resulting in serum levels lower than desired for therapy against some organisms.

**Laboratory Test Interference:** Enoxacin interferes with some assay procedures for the determination of urinary proteins, resulting in falsely high values. It is recommended that the heat coagulation method or reagent strip method be used during therapy with Enoxacin.

**Side Effects**

**Hyperactivity:** Hyperactivity reactions such as excitations and agitation have been some times reported (0.1 - 5.0% of the patients). Flashes have been infrequently reported (less than 0.1% of the patients). Glottic edema, facial edema, photosensitivity fever or erythema may rarely occur. The drug must be discontinued when these symptoms are observed.

**Shock:** Since shock symptoms may be infrequently observed (less than 0.1% of the patients) the patient should be observed carefully. The administration should be discontinued when such symptoms as tachypnea, chest pressure sensation, dyspnea and hypotension are observed and the patient should be treated appropriately.

**Renal:** Acute renal failure may rarely occur and transient elevations in BUN and serum creatinine levels may have occasionally been observed.

**Hematologic:** Transient increases in eosinophil counts and decreases in leukocyte counts, thrombocyte counts and hemoglobin levels may infrequently occur. If any such abnormalities are observed, administration should be discontinued.

**Gastrointestinal:** Nausea, vomiting, anorexia, abdominal pain, diarrhea, constipation may infrequently occur and stomatitis may rarely occur. Severe colitis associated with bloody stool, such as pseudomembranous colitis, has also been reported with the use of other new quinolones. If abdominal pain or frequent diarrhea develops the drug must be discontinued and appropriate measures taken.

**Elevation of SGOT, SGPT, and ALP, may infrequently occur and increase of bilirubin may rarely occur.**

**Central Nervous System:** Dizziness, headache and anaemia may infrequently occur and convulsions, drowsiness, feeling of numbness, tinnitus, light headache feeling, tremor or dizziness may rarely occur.

**Peripheral neuropathy that may be irreversible.**

**Muscular:** Rhabdomyolysis occurring with acute renal function disorder, characterized by myalgia, weakness, elevation of CPK, and elevation of plasma/uro myoglobin level, may occur. Therefore, appropriate precautions should be taken.

**Skin:** Since Lyell syndrome and Stevens Johnson syndrome may occur rarely, the patient must be monitored carefully. Administration of Enoxacin must be discontinued when any abnormality is observed and the patient should be treated appropriately.

**Others:** Palpitation,-precardial discomfort, miosis, hypoglycemic symptoms, demolished taste and rarely rashes 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 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, Filmcoat Tablets packed in blister strips of 2x10s in carton. List No. F 698

Manufactured by:
Abbott Laboratories (Pakistan) Ltd.
Landhi, Karachi.

**Abbott**

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