MEDLEY PHARMACEUTICALS

Mediflox *TABLETS*

(Levofloxacin)

DESCRIPTION: Mediflox is a formulation of Levofloxacin HCl (USP) in the form of film coated Tablets.

COMPOSITION:
Mediflox 250mg TABLETS:
Each film coated tablet contains:
Levofloxacin hemihydrates equivalent to Levofloxacin……250mg
(Medley's Specs)
MEDIFLOX 500mg TABLETS:
Each film coated tablet contains:
Levofloxacin hemihydrates equivalent to Levofloxacin……500mg
(Medley's Specs.)

CLINICAL PHARMACOLOGY .

(Antibacterial activity) Mediflox is broad spectrum antibacterial agent against Gram positive and Gram negative bacteria including anaerobes. Mediflox has shown strong antibacterial activities against Streptococcus pneumonia,Streptococcus pyogenes,Streptococcus hemolyticus,Escherchia coli, Pseudomonas aeroginosa,Haemophylus influenza and Neisseria gonorrhea

MECHANISM OF ACTION :
Levofloxacin inhibits DNA gyrase which result in abnormal linkages between opened DNA and the Gyrase negative supercoilling is impaired .So that efficient transcription of DNA into RNA and Subsequent protein synthesis is prevented .

PHARMACOKINETICS.
Orally administered Levofloxacin is rapidly and almost completely absorbed with peak plasma concentration being obtained within 1 hr. The absolute bioavallability is approximately 100%. Food has little effect on levofloxacin absorption .In plasma approximately 30-40% of Levofloxacin is bound to serum protein into body tissues and fluids a concentration of 8.3 ug/ml & 10.8 ug/ml respectively reached in 1 hr,in to lung tissues a concentration of 11.3 ug/ml were reached between 4 & 6 hrs.
Levofloxacin metablised to very little extent (5%). Levofloxacin is stereo chemically stable. Following oral administration levofloxacin is eliminated relatively slowly from the plasma (6-8 hrs).Excretion is primarily by renal route(85%) of the administration does. The pharmacokinetics of levofloxacin are affected by renal impairment with decreasing renal function, renal elimination is decreased.
LABORATORY TEST:

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- Laboratory tests have shown that maximum plasma level reaches after 0.5 hr at a dose of 20mg/kg of body except CNS fat. Levofloxacin concentrations in almost all tissues of the body were higher than the serum level demonstrating good transference to tissues. Drug concentration is high in the main organs kidneys, liver & lowest in the brain.

INDICATIONS:

- Mediflox is indication in the treatment of Pneumoniae, chronic bronchitis, diffuse bronchlolitis secondary infection and in chronic respiratory diseases.
- Laryngopharyngitis,cystitis,prostatitis,epididymitis,gonococcal urethritis.
- Intrauterine infection,cervictitis,uterineadnextis,bartholinitis.
- Secondary infection in traumatic wounds.
- Bacterial dysentery,infection enteritis,salmonella enteritis,cholera.
- Penodontitis,pericoronitis,gnathitis.
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CONTRAINDICATIONS:

Mediflox is contraindicated in patients with known hypersensitivity to any quinolone antibacterial agent.

PRECAUTIONS: If hypersensitivity occurs the drug should be discontinued to prevent the development of resistance, susceptibility to the drug should be determined before use. The duration of use should be limited to the minimal time required for treatment.

DRUG INTERACTIONS:

There are reports of convulsions of other quinolones used in combination with NSAID's of phenylacetate/propionic acid and derivatives, Antacids containing aluminium or magnesium and drugs containing iron may interfere with Levofloxacin resulting attenuation of the efficacy of levofloxacin, so the product should be administered carefully.

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS.

- Fluoroquinolones, including Levofloxacin, have been associated with disabling and potentially irreversible serious adverse reaction that have occurred together, including:
  - Tendinitis and tendon rupture
  - Peripheral Neuropathy
  - Central nervous system effects

Discontinue Levofloxacin immediately and avoid the use of Fluoroquinolones, including Levofloxacin in patients who experience any of these serious adverse reactions.

- Fluoroquinolones, including Levofloxacin may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Levofloxacin in patients with known history of myasthenia gravis.
- As fluoroquinolones, including Levofloxacin have been associated with serious adverse reactions, reserve Levofloxacin for use in patients who have no alternative treatment options for the following indications:
  - Acute exacerbation of chronic bronchitis
  - Acute sinusitis
  - Acute uncomplicated cystitis

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ADVERSE REACTION :

Following adverse reaction have been reported following the use of levofloxacin.

HYPERSENSITIVITY:

Including anaphylactic symptoms, Edema, urticaria, shock and rash or pruritis may occur infrequently.

RENAL:

An increase in BUN may rarely occur and may rarely cause acute renal failure.

HEPATIC:

An increase in S-GOT, SGPT and total bilirubin may occur infrequently.

HEMATOLOGIC:

A decrease in leukocytes,erythrocytes,hemoglobin or an increase in eosinophil may occur infrequently.

GESTROINTESTINAL:

Nausea,vomiting,abdominal discomfort,diarrhea.

Musculoskeletal system and peripheral nervous system

Tendinitis/Tendon rupture,Muscle pain/ weakness,Joint pain,Joint swelling,Peripheral Neuropathy

Central nervous system

Psychosis,Anxiety,Insomnia,Depression,Hallucinations,Suicidal thoughts,Confusion,Tremors

Other Adverse Reaction include:

Exacerbation of Myasthenia gravis,Ringing or buzzing in the ears,Headache,Abnormally rapid or irregular heart beat,Skin rash,Fatigue,Vision problem,Trouble falling asleep

USE DURING PREGNANCY OR LACTATION:

Since safety during pregnancy has not been established, this product should not be administered to pregnant women. Since it is excreted in breast milk, it is recommended that nursing mother refrain from using this product.

PAEDIATRIC USE:

Since the product safety for use by children has not been established, this product should not be administered to children.

DOSAGE AND ADMINISTRATION:

Acute Bacterial Exacerbation of Chronic Bronchitis; 250mg BID or 500mg OD for 7 days.
Acute Maxillary Sinusitis; 250mg BID or 500mg OD for 10-14 days.
Complicated UTI; 250mg OD for 10 days.
Uncomplication skin and soft tissue infection; 250 mg BID or 500mg OD for 7 days.
Acute pyelonnephritis; 250mg OD for 10 days.
Mediflox tablets may be taken during meals or between meals. Mediflox tablets should be taken two hours before iron salts, antacids administration since reduction of absorption may occur.

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STORAGE:

Store at controlled room temperature (15*C-30*C)

Presentation:

Mediflox 250mg tabs.
Alu Alu blister pack of 1x10's.
Mediflox 500mg tabs.
Alu Alu bilster pack of 1x10's.

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