Effiflox® Tablets / Infusion
(Levofloxacin)

COMPOSITION:

Effiflox® **250mg Tablets:**
Each film coated tablet contains:
Levofloxacin Hemihydrate USP
equivalent to Levofloxacin……250mg

Effiflox® **500mg Tablets:**
Each film coated tablet contains:
Levofloxacin Hemihydrate USP
equivalent to Levofloxacin…..500mg

Effiflox® **Infusion:**
Each 100ml contains:
Levofloxacin Hemihydrate USP
equivalent to Levofloxacin……..500mg

DESCRIPTION:
Levofloxacin is a fluoroquinolone antibiotic available for oral or intravenous administration. Levofloxacin is the optically active L-isomer of ofloxacin. It has a slightly longer half-life than ofloxacin and can be administered once-daily
It inhibits bacterial DNA gyrase, a type II topoisomerase. Topoisomerases alter DNA by introducing superhelical twists into double-stranded DNA and by facilitating unwinding of DNA strands. The molecular weight of levofloxacin is 361.40gm

INDICATIONS AND USAGE:
Effiflox® tablets / injection are indicated for the treatment of adults (18 years of age) with mild, moderate and severe infections caused by susceptible strains of the designated microorganisms in the conditions listed below. Effiflox® injection is indicated when intravenous administration offers a route of administration advantageous to the patient (e.g., patient cannot tolerate an oral dosage form)

Acute bacterial sinusitis due to Streptococcus pneumoniae, Haemophilus influenzae or Moraxella catarrhalis

Acute bacterial exacerbation of chronic bronchitis due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae* or *Moraxella catarrhalis*

Nosocomial pneumonia due to methicillin-susceptible *Staphylococcus aureus, Pseudomonas aeruginosa, Serratia marcescens, Escherichia coli, Klebsiella pneumoniae, Haemophilus influenzae* or *Streptococcus pneumoniae*. Adjunctive therapy should be used as clinically indicated. Where *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal-lactam is recommended

Community-acquired pneumonia due to *Staphylococcus aureus, Streptococcus pneumoniae* (including multi-drug-resistant strains [MDRSP])*, *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Chlamydia pneumoniae, Legionella pneumophila* or *Mycoplasma pneumoniae* *MDRSP (multi-drug resistant *Streptococcus pneumoniae*) isolates are strains resistant to two or more of the following antibiotics: penicillin (MIC 2 µg/mL), 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim / sulfamethoxazole

Complicated skin and skin structure infections due to methicillin susceptible *Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes* or *Proteus mirabilis*

Uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to *Staphylococcus aureus* or *Streptococcus pyogenes*

Chronic bacterial prostatitis due to *Escherichia coli, Enterococcus faecalis* or *Staphylococcus epidermidis*

Complicated urinary tract infections (mild to moderate) due to *Enterococcus faecalis, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis* or *Pseudomonas aeruginosa*

Acute pyelonephritis (mild to moderate) caused by *Escherichia coli*

Uncomplicated urinary tract infections (mild to moderate) due to *Escherichia coli, Klebsiella pneumoniae* or *Staphylococcus saprophyticus*

Inhalational anthrax (post-exposure) to prevent the development of inhalational anthrax following exposure to *Bacillus anthracis*

CONTRA-INDICATIONS:
Levofloxacin is contra-indicated in persons with a history of hypersensitivity to levofloxacin, quinolone antimicrobial agents or any other components of this product

WARNINGS:

Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug
Selection of a fluoroquinolone for the treatment or prevention of an infection should be limited to those conditions that are proven or strongly suspected to be caused by bacteria

Hepatotoxicity
Post-marketing reports of severe hepatotoxicity (including acute hepatitis and fatal events) have been received for patients treated with levofloxacin. No evidence of serious drug-associated hepatotoxicity was detected in clinical trials of over 7,000 patients. Severe hepatotoxicity generally occurred within 14 days of initiation of therapy and most cases occurred within 6 days. Most cases of severe hepatotoxicity were not associated with hypersensitivity. The majority of fatal hepatotoxicity reports occurred in patients 65 years of age or older and most were not associated with hypersensitivity. Levofloxacin should be discontinued if the patient develops signs and symptoms of hepatitis

The safety and efficacy of levofloxacin in paediatric patients, adolescents (under the age of 18 years), pregnant women, and nursing women have not been established. There is a risk of serious and occasionally fatal hypersensitivity reactions after multiple doses. Treatment should be discontinued at the first appearance of skin rash, jaundice or any other sign of hypersensitivity and supportive measures should be instituted. Risk of *Clostridium difficile*-associated diarrhoea (CDAD) should be considered

PRECAUTIONS:
Administer levofloxacin with caution in the presence of renal insufficiency. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of levofloxacin may be reduced. In patients with impaired renal function (creatinine clearance <50mL/min), adjustment of the dosage regimen is necessary to avoid the accumulation of levofloxacin due to decreased clearance

SIDE-EFFECTS:
The symptomatic adverse reactions produced by levofloxacin are more or less tolerable and if they become severe, they can be treated symptomatically, these include flatulence, dizziness, diarrhoea, anxiety, restlessness, constipation, abdominal pain, confusion, pruritus, hallucination, dyspepsia, depression, nightmares

Peripheral neuropathy: This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent
If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolones antibacterial drug, unless the benefit of continued treatement with a fluoroquinolone outweighs the risk

DRUG INTERACTIONS:
Levofloxacin is known to interact with other drugs like cyclosporin A, theophyllin, warfarin (Na). These interactions are sometimes beneficial and sometimes may pose threats to life always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required

DOSAGE:
Unless otherwise prescribed, the following guideline doses are recommended:
Patients with Normal Renal Function

Infection	Unit Dose	Freq.	Duration	Daily Dose
Comm. acquired pneumonia	500mg	q24h	7-14 days	500mg
Acute bacterial sinusitis	500mg	q24h	10-14 days	500mg
Acute bacterial exacerbation of chronic bronchitis	500mg	q24h	7 days	500mg
Uncomplicated SSSI	500mg	q24h	7-10 days	500mg
Chronic bacterial prostatitis	500mg	q24h	28 days	500mg
Complicated UTI	250mg	q24h	10 days	250mg
Acute pyelonephritis	250mg	q24h	10 days	250mg
Uncomplicated UTI	250mg	q24h	3 days	250mg

Since only limited data are available on the compatibility of levofloxacin intravenous injection with other intravenous substances, **additives or other medications should not be added to** Effiflox® **injection in single-use vials or infused simultaneously through the same intravenous line. I**f the same intravenous line is used for sequential infusion of several different drugs, the line should be flushed before and after infusion of Effiflox® injection with an infusion solution compatible with Effiflox® injection and with any other drug(s) administered via this common line

Vial	Dosage Strength	Infusion Time
100ml	500mg	60min

Duration of treatment depends on severity of the illness and on the clinical and biological course

OR
As directed by the physician

STABILITY:
See expiry on the pack

PRESENTATIONS:
Effiflox® 250mg tablets in a pack of 10's
Effiflox® 500mg tablets in a pack of 10's
Effiflox® 500mg/100ml infusion

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light, humidity and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

ایفی فلاکس ٹیبلٹ / انفیوژن
(لیوو فلاکسا سن)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی
تنبیہ: انجکشن کے ایک ہونے، ڈھندلا ہونے یا اس میں کوئی غیر حل پزیر
شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

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