• Uncomplicated cystitis (see section 4.4) In above-mentioned infections, Levofloxacin tablets product should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for **the treatment of these infections.**

• Inhalation Anthrax: postexposure prophylaxis and curative treatment (see section 4.4)

• Acute exacerbation of chronic obstructive pulmonary disease including bronchitis.

In above-mentioned infections, Levofloxacin tablets product should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for **the treatment of these infections.**

Levofloxacin tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Levofloxacin tablets are administered once or twice daily. The dosage depends on the type and severity of the infection and the sensitivity of the presumed causative pathogen.

Levofloxacin tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin; given the bioequivalence of the parenteral and oral forms, the same dosage can be used.

Posology

The following dose recommendations can be given for Levofloxacin:

Dosage in patients with normal renal function (creatinine clearance > 50ml / min)

Indication	Daily dose regimen (according to severity)	Duration Of treatment
Acute bacterial sinusitis	500 mg once daily	10 -14 days
Acute bacterial exacerbations of chronic bronchitis	500 mg once daily	7 – 10 days
Community-acquired pneumonia	500 mg once or twice daily	7 – 14 days
Pyelonephritis	500 mg once daily	7-10 days
Uncomplicated cystitis	250 mg once daily	3 days
Complicated urinary tract infections	500 mg once daily	7 – 14 days
Chronic bacterial prostatitis	500 mg once daily	28 days
Complicated Skin and soft tissue infections	500mg once or twice daily	7 – 14 days
Inhalation Anthrax	500 mg once daily	8 weeks

Special populations

Impaired renal function (creatinine clearance ≤ 50 ml / min).

	Dose regimen		
	250 mg / 24 h	**500 mg / 24 h**	**500 mg /12 h**
Creatinine clearance	first dose: 250 mg	first dose : 500 mg	first dose : 500 mg
50-20 ml / min	then : 125 mg / 24 h	then : 250 mg / 24 h	then : 250 mg / 12 h
19 – 10 ml / min	then : 125 mg / 48 h	then : 125 mg / 24 h	then : 125 mg / 12 h
< 10 ml / min (including haemodialysis and 1 CAPD	then : 125 mg / 48 h	then : 125 mg / 24 h	then : 125 mg / 24 h

1 No additional doses are required after haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

Impaired liver function

No adjustment of dosage is required since levofloxacin is not metabolised to any relevant extent by the liver and is mainly excreted by the kidneys.

Elderly Population

No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal function. (also see section 4.4 regarding QT interval prolongation).

Paediatric population

Levofloxacin is contraindicated in children and growing adolescents (less than 18 years of age) (see section 4.3).

Method of administration

Levofloxacin tablets should be swallowed without crushing and with sufficient amount of liquid. The tablets may be taken during meals or between meals. Levofloxacin tablets should be taken at least two hours before or after iron salts, zinc salts, magnesium-or aluminium containing antacids or didanosine (only didanosine formulations with aluminium or magnesium containing buffering agents), and sucralfate administration since reduction of absorption can occur (see section 4.5).

4.3 Contraindications

Levofloxacin 250 mg & 500mg film-coated tablets must not be used:

- in patients hypersensitive to levofloxacin or other quinolones or to any of the excipients listed in section 6.1
- in patients with epilepsy,
- in patients with history of tendon disorders related to fluoroquinolone administration,

Methicillin-resistant Staphylococcus aureus (MRSA)

Methicillin- resistant S. Aureus are very likely to possess co- resistance to flouroquinolones, including levofloxacin. Therefore levofloxacin is not recommended for the treatment of known or suspected MRSA infections unless laboratory results have confirmed susceptibility of the organism to levofloxacin (and commonly recommended antibacterial agents for the treatment of MRSA-infections are considered inappropriate)..

Levofloxacin may be used in the treatment of Acute Bacterial Sinusitis and Acute Exacerbation of Chronic Bronchitis when these infections have been adequately diagnosed.

Resistance to fluoroquinolones of E. coli – the most common pathogen involved in urinary tract infections – varies across the European Union. Prescribers are advised to take into account the local prevalence of resistance in E. coli to fluoroquinolones.

Inhalation Anthrax: Use in humans is based on in vitro Bacillus anthracis susceptibility data and on animal experimental data together with limited human data.

Treating physicians should refer to national and/or international consensus documents regarding the treatment of anthrax.

Prolonged, disabling and potentially irreversible serious adverse drug reactions

Very rare cases of prolonged (continuing months or years), disabling and potentially irreversible serious adverse drug reactions affecting different, sometimes multiple, body systems (musculoskeletal, nervous, psychiatric and senses) have been reported in patients receiving quinolones and fluoroquinolones irrespective of their age and pre-existing risk factors. Levofloxacin Tablet should be discontinued immediately at the first signs or symptoms of any serious adverse reaction and patients should be advised to contact their prescriber for advice

Tendinitis and tendon rupture

Tendinitis and tendon rupture (especially but not limited to Achilles tendon), sometimes bilateral, may occur as early as within 48 hours of starting treatment with levofloxacin and have been reported up to several months after discontinuation of treatment in patients receiving daily doses of 1000 mg levofloxacin. The risk of tendonitis and tendon rupture is increased in older patients , patients with renal impairment, patients with solid organ transplants, and those treated concurrently with corticosteroids. Therefore, concomitant use of corticosteroids should be avoided. At the first sign of tendinitis (e.g. painful swelling, inflammation). treatment with Levofloxacin tablet should be discontinued and alternative treatment should be considered. The affected limb(s) should be appropriately treated (e.g. immobilisation). Corticosteroids should not be used if signs of tendinopathy occur.

Clostridium difficile-associated disease

6. Pharmaceutical particulars

6.1 List of Excipients

Starch

Lactose

Dibasic Calcium Phosphate

P.V.P.K- 30

Methyl Paraben

Propyl Paraben

Sodium Lauryl Sulphate

Purified water

Magnesium Stearate

Talcum

Aerosil

Sodium Starch Glycolate

Unicoat AFC Brown Colour (Red oxide of Iron & Titanium dioxide)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store in a cool (between 10°C & 25°C) dry & dark place. Protect from light. Keep all medicines out of reach of children.

6.5 Nature and contents of container

10 Tablets are packed in Alu-Alu blister, such 1 Blister is packed in monocarton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

M/s. Jeksam Pharmaceutical Co. Ltd,

No.19 Anam Str Omagba,

Phase 11, Onitsha,

Anambra state,

Nigeria

8. Marketing authorization number(s)

N.A.

9. Date of first authorization/renewal of the authorization

N.A.

10. Date of revision of the text

N.A

1.3.1 Summary of Product Characteristics (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

1.0 NAME OF THE MEDICINAL PRODUCT

Levofloxacin Tablets 500 mg

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Film Coated Tablet Contains:

Levofloxacin Hemihydrate USP

Eq. to Levofloxacin ..... 500 mg

Excipients ..... Q.S.

Colour: Red Oxide of Iron, Titanium Dioxide

3.0 PHARMACEUTICAL FORM:

Film coated Tablet

Brick red coloured, oval shaped, film coated tablets having breakline on one side and other side is plain.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications

In adults, Levofloxacin tablets are indicated for the treatment of the following infections (see sections 4.4 and 5.1):

• Acute bacterial sinusitis

In above-mentioned infections, Levofloxacin tablets product should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for **the treatment of these infections**

• Community-acquired pneumonia.

• Complicated skin and soft tissue infections / Complicated skin and skin structure infection. For the above-mentioned infections, Levofloxacin tablets should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the treatment of these infections.

• Acute pyelonephritis and complicated urinary tract infections (see section 4.4)

• Chronic bacterial prostatitis.