

Depending on the severity of the infection and on the presence of complicating factors or pathogens of moderate susceptibility, it may be necessary to increase the dose to up to 2 x 2 tablets daily.

Dosage in patients with impaired renal function: In patients with impaired renal function, the following dosages are recommended:
The initial dose is the same as the patients with normal renal function, whereas the maintenance dose should be reduced as follows:

Creatinine clearance

50 - 20 ml/min

< 20 ml/min

Haemodialysis or peritoneal dialysis

Maintenance dose

1/2 - 1 tablet every 24 hours

1/2 tablet every 24 hours

1/2 tablet every 24 hours

In individual instances, it may be necessary to increase the dosage (see above). Dosage in patients with impaired liver function: The excretion of Ofloxacin may be reduced in patients with severe impairment of liver function (e.g., cirrhosis with ascities). A maximum daily dose of 400mg ofloxacin should therefore not be exceeded.

Duration of treatment:

The duration of treatment depends on the response of the causative organism and on the clinical picture. As with antibacterial treatment in general, it is recommended that treatment with Ofloban be continued for at least 3 days after the body temperature has returned to normal and the symptoms have subsided. In most cases of acute infection, a course of treatment lasting 7 to 10 days is sufficient. In salmonellosis, the duration of treatment is usually 7 to 8 days, in shigellosis 3 to 5 days, and in intestinal infections caused by *E. coli* 3 days.

For un-complicated infections of the lower urinary tract, 3 days treatments is usually sufficient. In case of infections with beta-haemolytic streptococci (e.g., purulent tonsillitis or erysipelas), treatment must be continued for at least 10 days in order to prevent late complications such as rehumtic fever or inflammation of the renal glomeruli (glomerulonephritis). However, since beta-haemolytic streptococci are of varying susceptibility to Ofloxacin, treatment of such infections requires individual proof of susceptibility.

Until further experience is available, the duration of treatment should not exceed 2 months.

Administration:

Ofloban tablets should be swallowed without chewing with sufficient amounts of liquid (approx. 1/2 glass). They may be taken on an empty stomach or with meals.

Presentation:

Ofloban 200mg tablets: 1 x 10 film-coated tablets.

ہدایات: دوا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

تمام ادویات بچوں کی پہنچ سے دُور رکھیں۔

30°C سے کم درجہ حرارت پر رکھیں۔

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Ofloban Tablets 200mg

(Ofloxacin)



اوفلوبان ٹیبلٹس ۲۰۰ ملی گرام
(اوفلاکساسین)

Composition:

Ofloban Tablet 200mg: Each film-coated tablet contains 200 mg Ofloxacin as active ingredient.

Properties:

Ofloxacin, the active ingredient of Ofloban, is a bactericidal quinolone antibiotic.

Indications:

Bacterial infections due to Ofloxacin-susceptible micro-organisms, such as
- Acute, chronic, or recurrent lower respiratory tract infections (bronchitis), especially if caused by *Haemophilus influenzae* or other Gram-negative or multi-resistant pathogens, as well as by *staphylococcus aureus*.

- Pneumonia, especially if caused by problem pathogens such as *Echerichia coli*, *Klebsiella*, *Enterobacter*, *Proteus*, *Pseudomonas*, *Legionella*, or *Staphylococcus*. Since in outpatients pneumococci are the most frequent pathogens responsible for pneumonia. Ofloban is not the treatment of first choice in these patients.

- Chronic and recurrent infections of the ear, nose and throat, especially if caused by Gram-negative pathogens including *Pseudomonas*, or *Staphylococcus*. However, Ofloban is in general not indicated for the treatment of acute tonsillitis caused by betahaemolytic streptococci (see also under "Dosage and administration").

- Infection of soft tissues and skin.

- infections of the bones and joints.

- Abdominal infections including infections in the pelvis minor and bacterial enteritis.

- Infections of the kidney, urinary tract, and genital organs, gonorrhea. Prevention of infections due to Ofloxacin-susceptible pathogens (prophylaxis of infections, also by selective decontamination of the intestine) in patients with a significant reduction in resistance to infections (e.g., in neutropenic state).

Antibacterial spectrum:

The following micro-organisms may be regarded as susceptible:

Staphylococcus aureus (incl. methicillin-resistant stap.), *Staphylococcus epidermidis*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Escherichia coli*, *citrobacter*, *Klebsiella*, *Enterobacter*, *Hafnia*, *Proteus* (indole-negative and indole-positive strains), *Salmonella*, *Shigella*, *Yersinia enterocolitica*, *Campylobacter jejuni*, *Aeromons*, *Pleasiomonas*, *Vibrio Cholerea*, *Vibrio parahaemolyticus*, *Haemophilus influenzae*, *chlamydiae*, *Legionella*.

The following micro-organisms vary in their susceptibility:

Enterococci, *Streptococcus pyogenes*, *Strptococcus pneumonia* *Streptococcus viridans*, *Serratia marcescens*, *Pseudomonas aeruginosa*, *Acinetobacter*, *Mycoplasma hominis*, *Mycoplasma pneumoniae*, *Mycobacterium tuberculosis*, and *Mycobacterium fortuitum*. The following micro-organisms are usually resistant to Ofloxacin:

Ureaplasma urealyticum, *Nocardia asteroides*, *anaerobes* (e.g., *Bacteroides* spp., *Peptococcus*, *Peptostreptococcus*, *Eubacterium* spp., *Fusobacterium* spp., *Clostridium difficile*). Ofloxacin is not effective against *Treponema pallidum*.

Contraindications:

Ofloban must not be used

- In patients hypersensitive to Ofloxacin, other quinolones or any of the excipients (see under "Composition").

- In epileptics as well as in patients with a lowered cerebral seizure threshold due to pre-existing central nervous system lesions, e.g., after cerebrocranial injuries, inflammations in the region of the CNS, or stroke (increased risk of convulsive seizures).

- In children of adolescents in the growth phase, during pregnancy or in breast-feeding women (since - judging from animal experiments - risk of damage to the certilage of joints in the growing organism cannot be entirely excluded).

Special warnings and precautions:

Patients with a history of severe adverse reactions (e.g., inflammation of a tendon [tendinitis], severe neurological reactions) to other quinolones may be at increased risk of similar reactions to Ofloxacin.