

OFLOMED®
200 mg Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about OFLOMED

Ofloxed tablet for oral administration contains 200 mg ofloxacin with the following excipients: microcrystalline cellulose, lactose monohydrate, magnesium stearate, talc.

Ofloxacin is a broad-spectrum fluoroquinolone antibiotic. OFLOMED has bactericidal activity against a wide-range of gram-negative and gram-positive microorganisms.

OFLOMED is indicated for the treatment of adults with mild to moderate and severe infections caused by susceptible strains of microorganisms in the conditions listed below:

- Acute bacterial exacerbations of chronic bronchitis
- Community-acquired pneumonia
- Uncomplicated skin and skin-structure infections
- Acute, uncomplicated, urethral and cervical gonorrhoea
- Infections of the urethra and cervix
- Acute Pelvic Inflammatory Disease
- Uncomplicated cystitis
- Complicated urinary tract infections
- Prostatitis
- Bone and joint tissue infections
- Chronic and recurrent infections of the ear, nose and throat

This medicine may be used to treat other conditions as well such as treatment of bacterial gastroenteritis.

The way to take OFLOMED

Take OFLOMED as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage and duration of treatment are individualized on the basis of the condition under treatment. The dosage must not be changed without medical advice. The usual dose for adults of OFLOMED tablets is 200 mg to 400 mg orally every 12 h. The following dosage recommendations can be given for adults with normal renal function:

Indication	Dose	Duration
Acute bacterial exacerbations of chronic bronchitis	400 mg (2 tablets of 200 mg) every 12 hours	10 days
Community-acquired pneumonia	400 mg (2 tablets of 200 mg) every 12 hours	10 days
Skin and skin structure infections	400 mg (2 tablets of 200 mg) every 12 hours	10 days
Uncomplicated gonorrhoea	400 mg (2 tablets of 200 mg) single dose	1 day
Cervicitis / urethritis	300 mg (one and a half tablet of 200 mg) every 12 hours	7 days
Acute Pelvic Inflammatory disease	400 mg (2 tablets of 200 mg) every 12 hours	10 to 14 days
Uncomplicated cystitis due to E.coli or K.pneumoniae	1 tablet of 200 mg every 12 hours	3 days
Uncomplicated cystitis due to other pathogens	1 tablet of 200 mg every 12 hours	7 days
Complicated urinary tract infections	1 tablet of 200 mg every 12 hours	10 days

Prostatitis	300 mg (one and a half tablet of 200 mg) every 12 hours	6 weeks
Infections of the ear, nose and throat	1 tablet of 200 mg every 12 hours	7 to 10 days

OFLOMED tablets may be taken on an empty stomach or with meals. Try to take the tablets at the same time each day and drink fluids liberally.

Duration of treatment

Although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the immediate treatment and increase the likelihood that bacteria will develop resistance.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- History of hypersensitivity associated with the use of ofloxacin or any member of the quinolone antibiotics.
- History of tendon disorders related to treatment with an antibiotic of the fluoroquinolone class
- Epilepsy
- Glucose-6-phosphate dehydrogenase deficiency
- Children and adolescents in the growth phase
- Pregnancy and lactation

Precautions

- The safety and efficacy of this drug in pediatric patients, adolescents (under 18 years), pregnant women, and nursing mothers have not been established.
- This drug should be used with caution in patients with known risk for prolongation of the QT interval, myasthenia gravis, impaired renal or hepatic function, or history of psychotic disorder.
- Avoid prolonged exposure to sunlight during the treatment.
- Inform your doctor if you experience burning, tingling, numbness, weakness, pain, inflammation, or rupture of a tendon, if any symptom of an allergic reaction occurs or if severe diarrhea occurs during treatment.
- This drug should be used with caution in patients with a known or suspected central nervous system disorder that may predispose to seizures or in the presence of other risk factors that may predispose to seizures (e.g., certain drug therapy, renal dysfunction.)
- Caution should be taken when driving a car or operating machinery until you are sure that this drug is not causing dizziness or lightheadedness.
- Careful monitoring of blood glucose is recommended in diabetic patients. If you have diabetes and you are treated with insulin or an oral hypoglycemic drug and you develop a hypoglycemic reaction while you are taking this drug, you should stop taking this medication and consult your doctor.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. Sucralfate, iron, didanosine, multivitamins containing zinc and antacids containing aluminum, calcium or magnesium should not be taken within the two-hour period before or after taking this drug.

Use with caution with non-steroidal anti-inflammatory drugs, theophylline, probenecid, oral anticoagulants, antidiabetic agents, cimetidine, and cyclosporine, drugs known to prolong the QT interval.

Adverse reactions

This drug is generally well tolerated. The most reported side effects include: nausea, insomnia, headache, dizziness, diarrhea, vomiting, rash, pruritus and vaginitis in women, dysgeusia, abdominal pain.

Rarely reported adverse reactions include tendon pain, increased levels of liver enzymes, convulsions, confusion, agitation, anxiety, tremors, tachycardia, hypotension or allergic reactions.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

OFLOMED, ofloxacin 200 mg, pack of 10 tablets

Revision date: 12/2011

OFLT2/010