

MEDOFLOXINE TABLET

Ofloxacin (200mg)

In this leaflet:

1. What MEDOFLOXINE is used for
2. How MEDOFLOXINE works
3. Before you use MEDOFLOXINE
4. How to use MEDOFLOXINE
5. While you were using it
6. Side effects
7. Storage and disposal of MEDOFLOXINE
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What MEDOFLOXINE is used for
MEDOFLOXINE tablets are used to treat infection of:

- Urinary tract (kidneys and bladder)
- Respiratory tract (lungs and chest)
- Genital tract (male and female sex organs)

Your doctor may, however, prescribe MEDOFLOXINE for another reason. Ask your doctor if you have any questions about why MEDOFLOXINE has been prescribed for you.

How MEDOFLOXINE works

MEDOFLOXINE contains ofloxacin which belongs to is one of a group of medicines called fluoroquinolone antibacterial. It kills bacteria (germs). This should cure any infection that the germs have caused.

Before you use MEDOFLOXINE

- When you must not use it

Do not take MEDOFLOXINE if:

- you are allergic (hypersensitive) to ofloxacin or any other ingredient of the tablet
- you are allergic to other quinolone antibacterial agents
- you are pregnant or planning to become pregnant
- you are breast feeding
- you are a child or a growing adolescent or prepubescent
- you have a history, of epilepsy or a lowered seizure threshold
- you have a history of inflammation of tendon

Pregnancy and breast-feeding

If you are pregnant or trying for a baby ask your doctor or pharmacist for

advice before taking any medicine including MEDOFLOXINE.

Ofloxacin should not be administered during the pregnancy.

If you are breast-feeding a baby, you should discuss this with the doctor; ofloxacin is found in the milk in small amounts. Breast-feeding is not recommended.

- Before you start to use it

Tell your doctor or pharmacist if:

- you have a history of heart problem
- you have an illness called 'myasthenia gravis' (muscle weakness).
- you have a history of epilepsy or central nervous system disorder
- you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- You have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial medicines, including Medofloxine, if you have experiences any serious adverse in the past when taking a fluoroquinolone (see section Things to be careful of and side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. It is important to tell the doctor if you are taking:

- medicines for gastric problem (antacids)

How to use MEDOFLOXINE

- How much to use

The dosage range for adult is 200-800mg daily, preferably in the morning and treatment duration should not exceed 2 months. Your doctor will tell you how much "MEDOFLOXINE" to take and when to take it. The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking the medicine and your response to treatment. Ask your doctor to explain more.

MEDOFLOXINE tablets should be swallowed whole with sufficient liquid before or during meal times. The dose should not be taken within two hours of taking an antacid, heartburn medicine (sucralfate) or medicine with iron in it.

- When to use it

Always take MEDOFLOXINE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how much MEDOFLOXINE to take and when to take it. The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking the medicine and your response to treatment. Ask your doctor to explain more.

The length of treatment is also variable; usually it is five to ten days. For some infections only a single dose is needed. You should not take the medicine for longer than two months.

- How long to use it

It is very important that you continue taking MEDOFLOXINE until you have finished all the tablets that the doctor has prescribed for you. Do not stop taking them even if you feel better. If you do your infection may come back and be more difficult to cure. Your doctor or pharmacist can tell you more.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember, unless it is almost the time for your next dose.

MEDOFLOXINE TABLET

Ofloxacin (200mg)

Never take two doses together to make up for the forgotten dose.

- If you use too much (overdose)

Contact your doctor or pharmacist straight away or go to the emergency department of your local hospital at once. Always take the container with you, if possible, even if it is empty.

While you are using it

- Things you must do

During your treatment with MEDOFLOXINE you should avoid excessive sunlight, such as sunbathing or sunbeds, as in rare cases this can cause a skin reaction (photosensitivity).

If you have to have your urine tested during MEDOFLOXINE treatment, tell the laboratory you are taking MEDOFLOXINE. It can give false results for some tests.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give MEDOFLOXINE to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Medofloxine, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you see the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.

- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of medofloxine therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Medofloxine, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Medofloxine and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

MEDOFLOXINE contains lactose, which is a sugar.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines:

MEDOFLOXINE can cause dizziness, sleepiness, sight difficulties and skill impairment. Do not drive or operate machinery.

Side effects

If you get any of the following side effects, stop taking MEDOFLOXINE and contact your doctor straight away:

- Fleabite-like haemorrhages
- Headache, sleep disturbance, vivid dream
- Unsteady gait and tremor
- Visual disturbance
- Numbness and tingling in the limbs
- Skin rash or peeling skin, itchy or lumpy skin
- Pain or tenderness in any joint
- Swelling of face or lips, wheeziness or difficulty breathing
- Racing heartbeat
- Diarrhoea, loss of appetite
- Abdominal pain
- Nausea and vomiting

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

Do not worry about this list of possible effects; you may not have any of them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [(Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))]

Storage and disposal of MEDOFLOXINE

MEDOFLOXINE TABLET

Ofloxacin (200mg)

- Storage

Keep out of the reach and sight of children.

Store below 30°C in the original package in a dry place

Serial Number

NPRA (R4/1)290120/00017

- Disposal

Do not use after the expiry date stated on the carton and blister.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

MEDOFLOXINE 200mg tablets are white, round, convex, film coated tablets with diameter of nucleus 9.5 mm.

They are packed in blisters of polyvinylchloride film and aluminium foil, with patient information leaflet, in a cardboard carton. Packs of 100 tablets are available.

- Ingredients

- Active ingredient

Each MEDOFLOXINE 200mg tablet contains contains 200mg ofloxacin.

- Inactive ingredients

MEDOFLOXINE 200mg tablets also contain: The other ingredients are: croscarmellose sodium, povidone, lactose, microcrystalline cellulose, magnesium stearate, hydroxypropylmethyl cellulose, titanium dioxide and polyethylene glycol.

- MAL No.

MEDOFLOXINE 20mg Tablet
MAL19921114AZ

Manufacturer

MEDOCHEMIE LTD, 1-10,
Constantinopouleos Street, 3011
Limassol, Cyprus

Product Registration Holder

KOMEDIC SDN BHD, 4 Jalan PJS
11/14, Bandar Sunway, 46150 Petaling
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Date of revision

16/11/2021