

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION**

**PATIENT MEDICATION INFORMATION**

**PrMOXIFLOXACIN**

**Moxifloxacin Tablets**

**400 mg Moxifloxacin (as moxifloxacin hydrochloride)**

House Standard

Read this carefully before you start taking **MOXIFLOXACIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MOXIFLOXACIN**.

**Serious Warnings and Precautions**

- Fluoroquinolone antibiotics, like **MOXIFLOXACIN**, are related to disabling and possibly long lasting effects such as:
  - inflamed tendon (tendonitis), tendon rupture.
  - nerve damage (peripheral neuropathy).
  - problems in the brain such as:
    - convulsions
    - nervous breakdown
    - confusion
    - and other symptoms
- Fluoroquinolone antibiotics, like **MOXIFLOXACIN**:
  - have lengthened the heartbeat (QT prolongation)
  - have led to serious allergic reactions, including death
  - may be related to increased tendonitis (inflamed tendon)
  - may worsen myasthenia gravis (a muscle disease)
  - may lead to seizures and nervous breakdowns. Tell your doctor if you have brain or spinal cord problems (such as epilepsy)
  - may cause liver injury which may lead to death
- For further information and symptoms see:
  - the “To help avoid side effects and ensure proper use,...” section
  - the “What are possible side effects from using **MOXIFLOXACIN**?” section

Talk to your doctor to see if **MOXIFLOXACIN** is right for you.

**What is **MOXIFLOXACIN** used for?**

Your doctor has prescribed **MOXIFLOXACIN** because you have a certain type of bacterial infection.

Antibacterial drugs like **MOXIFLOXACIN** treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, **MOXIFLOXACIN** should be used exactly as directed. Misuse or overuse of **MOXIFLOXACIN** could lead to the growth of bacteria that will not be killed by **MOXIFLOXACIN** (resistance). This means that **MOXIFLOXACIN** may not work for you in the future. Do not share your medicine.

**How does **MOXIFLOXACIN** work?**

**MOXIFLOXACIN** is an antibiotic. It kills many of the types of bacteria that can infect the lungs, sinuses, abdomen, and skin.

**What are the ingredients in **MOXIFLOXACIN** Tablets?**

Medicinal ingredients: 400 mg of moxifloxacin as moxifloxacin hydrochloride

Non-medicinal ingredients: Cellulose microcrystalline, sodium starch glycolate, povidone and magnesium stearate.  
Coating Ingredients: Opadry Pink 03B54025: It contains hypromellose, titanium dioxide, macrogol & iron oxide red.

**MOXIFLOXACIN Tablets come in the following dosage forms:**

400mg Tablets - Dull red coloured, modified capsule shaped, film coated tablets debossed with 'E 18' on one side and 'Plain' on the other side. Available in blister pack sizes of 3 x 10's and HDPE pack of 30's, 100's & 1000's count.

**Do not use MOXIFLOXACIN if:**

- you are allergic to moxifloxacin hydrochloride or other fluoroquinolone antibiotics.
- you are allergic to any other ingredient in the formulation (see "What are the ingredients in MOXIFLOXACIN Tablets?").

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MOXIFLOXACIN. Talk about any health conditions or problems you may have, including if you:**

- have or have a family history of irregular heart rhythm (such as QT prolongation).
- have or have had heart problems such as heart failure, an irregular heartbeat, or a slow heartbeat.
- have low potassium blood levels (see "The following may interact with MOXIFLOXACIN:").
- have a history of seizures.
- are pregnant, planning to become pregnant, or if you are breast feeding.
- are less than 18 years of age.
- have a history of tendon problems (such as pain, swelling or rupture of a tendon) related to the use of fluoroquinolone antibiotics.
- have myasthenia gravis (a muscle disease).
- have diabetes as MOXIFLOXACIN may affect blood sugar levels. MOXIFLOXACIN may also affect blood sugar levels in those without diabetes.
- have an aortic aneurysm which is an abnormal bulge in a large blood vessel called the aorta.
- have or if anyone in your family has a condition called aneurysm disease which is an abnormal bulge in any large blood vessel in the body.
- have an aortic dissection which is a tear in the wall of the aorta.
- have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis or Behcet's disease.
- have high blood pressure.
- have atherosclerosis, which is a hardening of your blood vessels.

**Other warnings you should know about:**

*Blood Sugar Changes*

Medicines like MOXIFLOXACIN can cause blood sugar levels to rise and drop in patients with diabetes. Serious cases of hypoglycemia (low blood sugar levels) that caused coma or death have been seen with medicines like moxifloxacin hydrochloride. If you have diabetes, check your blood sugar levels often while taking MOXIFLOXACIN.

**While taking MOXIFLOXACIN:**

- Avoid too much sunlight or artificial ultraviolet light (such as sunlamps).
- Contact your doctor if a sunburn or rash occurs.
- Do not drive or use machinery if you feel dizzy or lightheaded.

Quinolones, including MOXIFLOXACIN have been associated with an enlargement or "bulge" of a large blood vessel called the aorta (aortic aneurysm) and a tear in the aorta wall (aortic dissection).

- The risk of these problems is higher if you:
  - are elderly
  - have or anyone in your family has had aneurysm disease

- have an aortic aneurysm or an aortic dissection
  - have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis or giant cell arteritis or Behcet's disease
  - have high blood pressure or atherosclerosis
- If you experience sudden, severe pain in your abdomen, chest or back, a pulsating sensation in your abdomen, dizziness or loss of consciousness, get immediate medical help.

Tendon problems can happen within the first 48 hours of treatment.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with MOXIFLOXACIN:**

- Antacids or vitamin/mineral supplements
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Antidiabetic medicines (such as, insulin, glyburide, glibenclamide)
- Quinidine, procainamide, amiodarone, sotalol, cisapride<sup>b</sup>, erythromycin, antipsychotics, tricyclic antidepressants, diuretics (furosemide, hydrochlorothiazide).

<sup>b</sup> no longer marketed in Canada

**How to take MOXIFLOXACIN:**

- You must take MOXIFLOXACIN exactly as prescribed by your doctor. YOU SHOULD NOT INCREASE THE PRESCRIBED DOSE.
- You can take MOXIFLOXACIN with or without food.
- You should drink lots of fluids while taking MOXIFLOXACIN.
- If your doctor decides to stop the treatment, dispose of all unused MOXIFLOXACIN tablets.

**Usual dose:**

- Take one 400 mg MOXIFLOXACIN tablet once a day.
- Swallow each MOXIFLOXACIN tablet whole with a drink of water. Do not crush or chew MOXIFLOXACIN tablets.
- If you are taking antacids or vitamin/mineral supplements which contain magnesium or aluminium, take MOXIFLOXACIN at least 4 hours before or 8 hours after taking the supplement or antacid.
- Your doctor has decided on the best dose for you and for how long based on your needs.
- The usual length of treatment with MOXIFLOXACIN is 5-10 days. IT IS IMPORTANT TO COMPLETE THE FULL LENGTH OF TREATMENT, EVEN IF YOU BEGIN TO FEEL BETTER.

**Overdose:**

If you think you have taken too much MOXIFLOXACIN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take your tablet you should take it as soon as you remember on the same day. If you do not take your tablet on one day, take your normal dose (one tablet) on the next day. Do not take a double dose to make up for a forgotten dose. If you are unsure about what to do, consult your healthcare professional.

**What are possible side effects from using MOXIFLOXACIN?**

All medicines, including MOXIFLOXACIN, can cause side effects, although not everyone gets them.

These are not all the possible side effects you may feel when taking MOXIFLOXACIN. If you have any side effects not listed here or if conditions worsen or do not improve then:

- contact your healthcare professional.
- see the “To help avoid side effects and ensure proper use,...” section.

Stop taking MOXIFLOXACIN and contact your doctor if:

a) you have symptoms of an allergic reaction such as:

- rash, hives, blistering or other skin reaction
- swelling of the mouth, throat, limbs
- difficulty breathing
- irregular or rapid heartbeat, or fainting spells

b) you have pain, swelling or rupture of a tendon. These side effects may last more than 30 days. You should:

- rest
- avoid physical exercise

c) you have neuropathy (damage to the nerves) with symptoms such as:

- pain, burning, tingling, numbness or weakness

d) you have severe diarrhea (bloody or watery) with or without:

- fever
- stomach pain or tenderness

You may have Clostridium difficile colitis (bowel inflammation). See your doctor right away.

Other side effects include:

- your eyesight worsens or changes. These side effects may last more than 30 days. See your doctor or eye specialist right away.
- nausea, dizziness
- worsening of myasthenia gravis (a muscle disease) with symptoms such as:
  - weakness
  - difficulty walking, swallowing, drooping eyelids

Do not use MOXIFLOXACIN if you have this condition.

- mental problems such as:
  - confusion, headache, shaking
  - hallucinations, depression, agitation
  - difficulty sleeping, anxiety, nervousness, suicidal thoughts

These side effects may last more than 30 days.

Contact your doctor if you have suicidal thoughts.

Self-Limiting Side Effects:

- feeling lightheaded
- insomnia (difficulty sleeping)
- nightmares

If any of these affect you severely, tell your doctor or pharmacist.

<b>Serious Side Effects and What to do About Them</b>			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>			
Irregular heartbeat or fainting spells			√
Mental health problems: <ul style="list-style-type: none"> <li>• anxiety</li> <li>• confusion</li> <li>• depression</li> <li>• feeling agitated</li> <li>• restless or nervous</li> <li>• suicidal thoughts or actions</li> <li>• hallucinations</li> <li>• inability to think clearly or pay attention</li> <li>• memory loss</li> <li>• paranoia or loss of touch with reality</li> </ul> (These side effects may last more than 30 days)			√
Neurological problems: <ul style="list-style-type: none"> <li>• seizures/convulsions</li> <li>• tremors</li> </ul>		√	
Nervous system side effects: <ul style="list-style-type: none"> <li>• symptoms of neuropathy (damage to the nerves): numbness, tingling, pain, burning or weakness</li> </ul>			√
Rise in the pressure within your skull: <ul style="list-style-type: none"> <li>• blurred or double vision</li> <li>• headaches</li> <li>• nausea</li> </ul>		√	
<b>Tendon pain, inflammation, or rupture</b> (these side effects may last more than 30 days)			√
<b>Symptoms of an allergic reaction (which may lead to death):</b> <ul style="list-style-type: none"> <li>• rash</li> <li>• hives</li> <li>• rapid heartbeat</li> <li>• difficulty breathing</li> <li>• difficulty swallowing</li> <li>• swelling of face, lips, or tongue</li> </ul>			√
<b>Liver problems with symptoms such as yellowing of the skin and/or eyes, nausea, abdominal pain, dark urine, and pale stools</b>			√
<b>Symptoms of a severe bowel condition (Clostridium difficile colitis):</b> <ul style="list-style-type: none"> <li>• persistent diarrhea</li> <li>• bloody or watery diarrhea</li> <li>• abdominal or stomach pain/cramping</li> <li>• blood/mucus in stool</li> </ul>			√

<b>VERY RARE</b>			
Hypoglycemia (low blood sugar) such as: <ul style="list-style-type: none"> <li>• change in mood</li> <li>• change in vision</li> <li>• confusion</li> <li>• dizziness</li> <li>• fast heartbeat</li> <li>• feeling faint</li> <li>• headache</li> <li>• hunger</li> <li>• shaking</li> <li>• sweating</li> <li>• weakness</li> </ul>		√	
<b>UNKNOWN</b>			
<b>Aortic aneurysm (abnormal bulge in a large blood vessel called the aorta) /Aortic dissection (tear in the wall of the aorta):</b> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• loss of consciousness</li> <li>• pulsating sensation in the abdomen</li> <li>• sudden, severe pain in abdomen, chest or back</li> </ul>			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

MOXIFLOXACIN tablets should be stored:

- Store at room temperature (15°C to 30°C).
- Keep out of reach and sight of children.

**If you want more information about MOXIFLOXACIN:**

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

This leaflet was prepared by Pro Doc Ltée, Laval, Quebec, H7L 3W9

Date of Revision: February 19, 2021.