

Applicant/PHCR:	Macleods Pharmaceuticals SA (Pty) Ltd
Product Name:	Moxifloxacin 100 mg tablets
Active Ingredient:	Moxifloxacin hydrochloride
Dosage Form:	Dispersible tablets
Date:	26 June 2026

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SCHEDULING STATUS: **S4**

LONXAVE 100 mg DT (dispersible tablets)

Moxifloxacin hydrochloride

Contains sugar (91 mg of Mannitol, 3,5 mg of Sucralose and 12,5 mg of Aspartame).

Read all of this leaflet carefully before you start taking LONXAVE 100 mg DT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **LONXAVE 100 mg DT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **LONXAVE 100 mg DT** is and what it is used for
2. What you need to know before you take **LONXAVE 100 mg DT**
3. How to take **LONXAVE 100 mg DT**
4. Possible side effects
5. How to store **LONXAVE 100 mg DT**
6. Contents of the pack and other information

1. What LONXAVE 100 mg DT is and what it is used for

LONXAVE 100 mg DT contains moxifloxacin as the active ingredient which belongs to a group of antibiotics called fluoroquinolones. **LONXAVE 100 mg DT** works by killing bacteria that cause infections. **LONXAVE 100 mg DT** is used in patients aged 18 years and above for treating the

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following bacterial infections when caused by bacteria against which moxifloxacin is active:

Infection of the sinuses, sudden worsening of long term inflammation of the airways (chronic bronchitis), infection of the lungs (pneumonia) acquired out of hospital, skin and soft tissue infections, and infections of the female upper genital tract.

2. What you need to know before you take LONXAVE 100 MG DT

It is important that you tell your doctor or healthcare professional if you suffer from any of the conditions mentioned below, if you are taking LONXAVE 100 mg DT or have been prescribed LONXAVE 100 mg DT .

Do not take LONXAVE 100 mg DT :

- If you are allergic to moxifloxacin or any of the other ingredients of **LONXAVE 100 mg DT** listed in section 6.
- If you have experienced side effects with the use of quinolone/fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder).
- If you have severe liver disease.
- If you are pregnant or breastfeeding.

Do not take **LONXAVE 100 mg DT** and inform your doctor if you were born with or have:

- any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart).
- a salt imbalance in the blood (especially low levels of potassium in the blood).
- a very slow heart rhythm (called 'bradycardia').
- a weak heart (heart failure).
- a history of abnormal heart rhythms.
- If you are taking other medicines that result in abnormal ECG changes (see section **Taking other medicines**). This is because **LONXAVE 100 mg DT** can cause changes on the ECG referred to

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as a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.

- If you have kidney damage and/or taking high blood pressure medicines that belong to the class ACE inhibitors / renin-angiotensin receptor blockers (see section **Taking other medicines**).
- If you have an enlargement or “bulge” of a large blood vessel (aortic aneurysm) or a previous episode of aortic dissection (a tear in the aortic wall) or a family history of aortic aneurysm/dissection or have other risk factors or existing predisposing conditions.
- If you experience convulsions (uncontrolled shaking, fits)

If you have been diagnosed with mitral and/or aortic valve regurgitation (conditions in which your heart's mitral/aortic valve do not close tightly.)

If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases paralysis)

Warnings and precautions

Inform your doctor:

The safety and efficacy of **LONXAVE DT 100 mg** in pregnant and breastfeeding women have not been established.

If you are taking medicines to correct the abnormal rhythm of the heart such as quinidine, procainamide, amiodarone and sotalol.

- If you suffer from myasthenia gravis (condition in which the muscles become weak and tire easily and in serious cases paralysis), taking **LONXAVE 100 mg DT** may worsen the symptoms of your disease.
- If you suffer from epilepsy.
- If you have or had any mental health problems.
- If you have a complicated infection of the female upper genital tract (e.g. associated with an

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abscess of the fallopian tubes and ovaries or of the pelvis), your doctor will prescribe an intravenous (IV) treatment and therefore treatment with **LONXAVE 100 mg DT** will not be appropriate.

- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease). Taking **LONXAVE 100 mg DT** with this condition may lead to breakdown of your red blood cells.
- **LONXAVE 100 mg DT** will not be prescribed to you if the infection you are suffering from is caused by a bacteria known as MRSA (methicillin-resistant *Staphylococcus aureus*). While taking **LONXAVE 100 MG DT**
- There is a chance that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. If so, stop taking **LONXAVE 100 mg DT** and seek medical advice immediately.
- **LONXAVE 100 mg DT** may cause a severe inflammation of the liver which could lead to life-threatening liver failure. If you suddenly feel unwell and/or are being sick and also have yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed please contact your doctor before taking any more **LONXAVE 100 mg DT**.
- If you develop a skin reaction or blistering / peeling of the skin contact your doctor immediately before you continue treatment.
- Quinolone antibiotics, including **LONXAVE 100 mg DT**, may cause convulsions. If this happens, stop taking **LONXAVE 100 mg DT** and contact your doctor immediately
- You may experience mental health problems even when taking quinolone antibiotics, including **LONXAVE 100 mg DT**, for the first time. In some cases depression or mental health problems have led to suicidal thoughts and self-endangering behaviour such as suicide attempts. If you develop such reactions, stop taking **LONXAVE 100 mg DT** and inform your doctor immediately.
- Stop taking **LONXAVE 100 mg DT** and inform your doctor immediately if you experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness.

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- You may develop diarrhoea whilst or after taking antibiotics including **LONXAVE 100 mg DT** . If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking **LONXAVE 100 mg DT** immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.

LONXAVE DT 100 mg may cause pain and inflammation of your tendons, even within 48 hours of starting treatment and up to several months after discontinuing **LONXAVE DT 100 mg** therapy. At the first sign of any pain or inflammation you should stop taking **LONXAVE DT 100 mg**, rest the affected limb(s) and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture

- Quinolone antibiotics, such as LONVAXE DT 100 mg may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking **LONXAVE 100 mg DT** .

Inform your doctor that you are taking **LONXAVE 100 mg DT** if you are to take a test for TB (tuberculosis).

Inform your doctor immediately if you are taking any high blood pressure medicines which belong to the group ACE inhibitors / renin-angiotensin receptor blockers. Use of fluoroquinolone antibiotics, including **LONXAVE 100 mg DT** , together with ACE inhibitors / renin-angiotensin receptor blockers can cause damage to your kidneys.

- Inform your doctor immediately if you have been diagnosed with mitral and/or aortic valve regurgitation (conditions in which your heart's mitral/aortic valve do not close tightly) Mitral valve regurgitation allows blood to flow backward in your heart and aortic valve regurgitation allows some of the blood that was pumped out of your heart's main pumping chamber (left ventricle) to leak back into it. You will be required to undergo a heart examination before you are prescribed **LONXAVE 100 mg DT** .
- If you have diabetes, consult your doctor before taking **LONXAVE 100 mg DT** . **LONXAVE 100**

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mg DT may cause disturbances in your blood sugar level, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar. Your doctor may wish to monitor your blood sugar during your treatment with **LONXAVE 100 mg DT** .

- If you develop problems with your vision, consult an ophthalmologist immediately.

Other medicines and LONXAVE 100 mg DT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking the following medicines before starting **LONXAVE 100 mg DT** :

- medicines that belong to the group of anti-dysrhythmics, medicines used to treat your heart rhythm abnormalities (e.g. quinidine, hydroquinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, ibutilide).
- antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride).
- tricyclic antidepressants (amitriptyline, imipramine, dothiepin, trimipramine, desimipramine).
- antimicrobial medicines (IV erythromycin, saquinavir, sparfloxacin, pentamidine, amphotericin B)
- antimalarials (halofantrine)
- antihistaminics (astemizole, mizolastine)
- cisapride (for heartburn and reflux), IV vincamine (increases blood flow), bepridil (for chest pain), diphemanil (for peptic ulcers)
- diuretics (water tablets), laxatives, enemas, corticosteroids, medicines used to slow the heart rate
- antacids, minerals and multi-vitamins, therefore, you should take these other medicines at least 4 hours before or 2 hours after taking your **LONXAVE 100 mg DT** tablets.
- warfarin (used to thin blood).
- antidiabetics (e.g. glibenclamide).
- nonsteroidal anti-inflammatory medicines (NSAIDs).
- charcoal.
- Medicines used to treat high blood pressure that belong to the group ACE inhibitors / renin-

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angiotensin receptor blockers (e.g. enalapril, captopril, perindopril, losartan, irbesartan, valsartan).

- Digoxin (a medicine used to treat heart failure).

LONXAVE with food and drink:

LONXAVE 100 mg DT can be taken with or without food (including dairy products).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LONXAVE 100 mg DT**.

Safety of **LONXAVE 100 mg DT** during pregnancy and breastfeeding has not been established.

Driving and using machines

Dizziness and lightheadedness may occur in some patients taking **LONXAVE 100 mg DT**. If you experience these symptoms you should evaluate your ability to drive or to operate machinery.

It is not always possible to predict to what extent **LONXAVE 100 mg DT** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **LONXAVE 100 mg DT** affects them.

3. How to take LONXAVE 100 MG DT

Do not share medicines prescribed for you with any other person.

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Always take **LONXAVE 100 mg DT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long your treatment with **LONXAVE 100 mg DT** will last. Do not stop treatment early. If you have the impression that the effect of **LONXAVE 100 mg DT** is too strong or too weak, talk to your doctor or pharmacist.

Take **LONXAVE 100 mg DT** with or without food, as your doctor has prescribed.

Recommended dosing:

4 x LONXAVE 100 mg DT once a day

The time you will take **LONXAVE 100 mg DT** for depends on your infection.

It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking **LONXAVE 100 mg DT** too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to **LONXAVE 100 mg DT**.

The recommended dose and duration of treatment should not be exceeded.

If you take more LONXAVE 100 mg DT than you should

If you have accidentally taken too much **LONXAVE 100 mg DT** get medical help immediately by calling your nearest doctor or healthcare professional.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take LONXAVE 100 MG DT

Take **LONXAVE 100 mg DT** as prescribed.

Take a missed dose if it was due fewer than 12 hours ago. If more than 12 hours have passed since the dose was due, you should omit the missed dose and take the next scheduled dose at the usual time.

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Do not take a double dose to make up for a forgotten dose.

If the patient vomits within 1 hour of taking **LONXAVE 100 mg DT**, the patient should take an extra dose. If vomiting occurs more than an hour after taking the dose, the patient does not need to take an extra dose and can take the next dose as usual when it is due.

If you stop taking LONXAVE 100 mg DT

If you stop taking this medicine too soon, your infection may not be completely cured. Talk to your doctor if you wish to stop taking your tablets before the end of the course of treatment.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4 Possible side effects

LONXAVE 100 mg DT can have side effects.

Not all side effects reported for **LONXAVE 100 mg DT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LONXAVE 100 mg DT**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **LONXAVE 100 mg DT** and tell your doctor immediately or go to the casualty department at your nearest hospital:

-hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to **LONXAVE 100 mg DT**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- psychiatric symptoms including confusion, severe depression, suicidal thoughts, aggression,

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extreme fear, hallucinations, or unusual behaviour.

- fever with a severe blistering, peeling and red skin rash or any severe skin reaction.
- seizures (have a "fit" or convulsion).
- nausea, stomach pain, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side-effects or if any of these symptoms are bothersome or do not go away:

Frequent side effects

- Headache, dizziness
- QT prolongation – causes fast heartbeat, fainting, chest pain
- Nausea and vomiting, stomach pain, diarrhoea
- Infections caused by fungi (oral and vaginal infections/thrush caused by Candida)

Less frequent side effects

- decreased appetite
- allergic reactions
- increased cholesterol, increased sugar levels, increased levels of uric acid
- numbness, tingling, pins and needles
- tremor (shake)
- difficulty concentrating
- drowsiness
- difficulty falling asleep
- unusual dreams
- disturbances of co-ordination and balance
- forgetfulness
- confusion

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- abnormally happy mood
- blurred vision
- ringing in the ears
- Anaemia (low red blood cell count), leukopenia (low white blood cell count), neutropenia (low numbers of special white blood cells – neutrophils), thrombocytopenia (decrease or increase of special cells necessary for blood clotting), prolonged prothrombin time or increased INR (decreased blood clotting)
- Anxiety reactions, restlessness/agitation
- Dyspnoea (difficulty in breathing including asthma)
- Blood-glucose disorders (high blood sugar – hyperglycaemia or low blood sugar - hypoglycaemia)
- Reduced skin sensation, smell disorders, impaired speech, hearing impairment including deafness (usually reversible)
- Temporary loss of vision
- Abnormal fast heart rhythm, syncope (fainting), high blood pressure, low blood pressure, unspecified abnormal heart rhythms, Torsade de Pointes (life-threatening irregular heart beat), cardiac arrest (stopping of heart beat)
- Dyspnoea (difficulty in breathing including asthma)
- flatulence (wind), gastroenteritis (inflammation of the stomach),
- Dysphagia (difficulty in swallowing), stomatitis (inflammation of the mouth), antibiotic-associated colitis (severe diarrhoea containing blood and/or mucus, which may be life-threatening)
- Impairment or failure of the kidneys (due to dehydration)
- SIADH (syndrome of inappropriate antidiuretic hormone secretion) which caused your body to retain too much water.

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- palpitations (rapid irregular action of heart)
- increased rate of heart beat
- asthma
- indigestion
- upset stomach
- taste disturbances
- skin rash
- itching
- increased sweating
- muscle or joint pain
- fatigue or lack of energy
- generally feeling unwell
- pain
- changes in shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist)
- heart murmur

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **LONXAVE 100 mg DT**.

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5. How to store LONXAVE 100 mg DT

Store at or below 30 °C.

Protect from light and moisture

Keep the blisters in the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Any expired or outdated medicines and unused medicines can be returned

To your nearest pharmacy.

Do not dispose of unused medicine in drains or sewerage systems

(e.g. toilets).

6. Contents of pack and other information

What LONXAVE 100 mg DT contains

The active ingredient is Moxifloxacin hydrochloride

Contains sugar (91 mg of Mannitol).

The Other ingredients are: Ethylcellulose, Isopropyl alcohol, Methacrylic acid copolymer, Purified water, Triethyl citrate, Mannitol, Microcrystalline cellulose, Sucralose, Sodium Chloride,

Crospovidone, Aspartame, Magnesium stearate, and Bitter Masker Flavour (OZ-378-740-5)

contains Acacia, 414, Sugar, Tapioca maltodextrin, Nature-identical flavouring substance(s), Artificial flavouring substance(s), Ascorbic acid, 300.

What LONXAVE 100 mg DT looks like and contents of the pack

LONXAVE 100 mg DT : Light yellow to mottled yellow colour, capsule shape, biconvex, uncoated dispersible tablets debossed with "I 75" on one side and breakline on the other side.

Blister pack:

Tablets are packed in cold form 25 µm OPA/45 µm aluminum foil/60 µm PVC as the forming material

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and 25 µ aluminium plain foil/ 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.

Pack size includes 10's, 28's, 30's and 100's Tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive, Bassonia Rock Ext 12,

Alberton, Gauteng

This leaflet was last revised in 26 May 2026

Registration numbers

LONXAVE 100 mg DT: 60/20.1.1/0617

Access to the corresponding Professional Information

The corresponding professional information can be accessed at

<https://www.macleodssaproducts.co.za> or email macleodsrso@macleodspharma.com or

contact 011 682 1169

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