

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB326 trade name][†]
Levofloxacin

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB326 trade name] is and what it is used for
2. What you need to know before you take [TB326 trade name]
3. How to take [TB326 trade name]
4. Possible side effects
5. How to store [TB326 trade name]
6. Contents of the pack and other information

1. What [TB326 trade name] is and what it is used for

[TB326 trade name] is a medicine used in children under 15 years of age to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB326 trade name] is also used on its own for the prevention of tuberculosis if you are under 15 years of age and at high risk of infection.

[TB326 trade name] contains the active substance levofloxacin, which belongs to a group of antibiotics called fluoroquinolones.

This product is for use in children. However, information from its use in adults is also included to give a fuller picture of the medicine's effects.

2. What you need to know before you take [TB326 trade name]

Do not take [TB326 trade name] if:

- you are allergic to levofloxacin, related antibiotics (quinolones and fluoroquinolones) such as moxifloxacin, ciprofloxacin or ofloxacin, or any of the other ingredients of [TB326 trade name] (listed in Section 6 below). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- you have ever had epilepsy
- you have ever had a problem with your tendons such as tendinitis that was related to treatment with a fluoroquinolone antibiotic.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

You must not take this medicine if any of the above applies to you. If you are not sure, talk to your health care provider before taking [TB326 trade name].

Warnings and precautions

Talk to your health care provider before taking [TB326 trade name]:

- If you are 60 years or older
- If you are using corticosteroids, sometimes called steroids (see “Other medicines and [TB326 trade name]” below)
- If you have received a transplant
- If you have ever had a fit (seizure)
- If you have had damage to your brain due to a stroke or other brain injury
- If you have kidney problems
- If you have something known as ‘glucose-6-phosphate dehydrogenase deficiency’ (a rare hereditary disease). If so, you are more likely to have serious problems with your blood when taking this medicine
- If you have ever had mental health problems
- If you have a peripheral nerve disorder (peripheral neuropathy)
- If you have ever had heart problems: caution should be taken when using [TB326 trade name], if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called ‘bradycardia’), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes or are taking vitamin K antagonists (e.g. warfarin), due to a possible increase in coagulation tests and/or bleeding (see section “Other medicines and [TB326 trade name]”)
- If you have been diagnosed with heart valve failure (regurgitation of the heart valves)
- If you are diabetic
- If you have ever had liver problems
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking [TB326 trade name] may worsen the symptoms of your disease
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- If 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, Turner or Sjögren's syndrome (an inflammatory autoimmune disease), or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints), or endocarditis (a heart infection))
- If you have ever developed a severe or peeling skin rash, blisters and / or mouth sores after taking levofloxacin.

Talk to your health care provider if any of the above apply to you.

When taking [TB326 trade name]

- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a health care provider immediately.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of levofloxacin. If you develop a skin reaction or blistering / peeling of the skin and/or mucosal reactions (see section 4, ‘Possible side effects’) contact your health care provider or seek medical attention immediately before you continue treatment.

- Try to keep out of direct sunlight while taking this medicine and for 2 days after you stop taking it. Your skin may become much more sensitive to the sun and may burn, tingle or severely blister. Therefore it is recommended you take the following precautions:
 - Always wear a hat and clothes which cover your arms and legs
 - Make sure you use high factor sun cream
 - Avoid sun beds
- [TB326 trade name] may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases, see section 4, 'Possible side effects'). Speak with your health care provider straightaway if you:
 - lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash
and you have any of the following
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of the white parts of your eyes, your nails or your skin
 - passing dark urine
 - passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- The risk of heart problems may increase with higher doses, therefore, you should keep to the prescribed dose.
- [TB326 trade name] can affect the bone marrow and lead to low levels of red and white blood cells. Your health care provider may carry out blood tests to count the cells in your blood if they think you may be affected in this way.
- There is a small risk 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 [TB326 trade name] and seek medical help immediately.
- Quinolone antibiotics, including [TB326 trade name], may cause convulsions. If this happens, stop taking [TB326 trade name] and contact your health care provider immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, inform your health care provider immediately prior to continuing treatment with [TB326 trade name].
- You may experience mental health problems even when taking quinolone antibiotics, including [TB326 trade name], for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-endangering behaviour such as suicide attempts (see section 4, 'Possible side effects'). If you develop such reactions, stop taking [TB326 trade name] and inform your health care provider immediately.
- You may develop diarrhoea whilst or after taking antibiotics including [TB326 trade name]. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking [TB326 trade name] immediately and consult your health care provider. You should not take medicines that stop or slow down bowel movement.
- Tell your health care provider right away if you feel sick or generally unwell, vomit, and have pain or severe discomfort in your belly. These may be signs of an inflammation of the pancreas (pancreatitis), which can be serious.
- [TB326 trade name] may occasionally cause pain and inflammation of your tendons like the one at the back of your heel, particularly if you are elderly or if you are also taking corticosteroids. At the first sign of any pain or inflammation you should stop taking [TB326 trade name], rest the affected limb and consult your health care provider immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. Inflammation and ruptures of tendons may occur even up to several months after discontinuing therapy with [TB326 trade name].
- If you have diabetes and are using medicines to control your blood sugar, you should monitor your blood sugar levels carefully, as [TB326 trade name] in such cases may lower blood sugar levels.

Other medicines and [TB326 trade name]

Please tell your health care provider if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because [TB326 trade name] can affect the way some other medicines work. Also some medicines can affect the way [TB326 trade name] work. In particular, tell your health care provider if you are taking any of the following medicines. This is because it can increase the risk of you getting side effects, when taken with [TB326 trade name]:

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage of your tendons.
- Vitamin K antagonists such as warfarin - used to thin the blood. You may be more likely to have a bleed. Your health care provider may need to take regular blood tests to check how well your blood can clot.
- Theophylline - used for breathing problems. You may be more likely to have a fit (seizure) if you take theophylline with [TB326 trade name].
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for relief of pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You may be more likely to have a fit (seizure) if taken with [TB326 trade name].
- Ciclosporin - used after organ transplants. You may be more likely to get the side effects of ciclosporin
- Medicines known to affect the way your heart beats. This include medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine), for psychiatric disorders (antipsychotics), for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin) and for pain or treatment of drug addiction (methadone).
- Probenecid (used for gout), cimetidine (used for stomach ulcers and heartburn), frusemide (used for high blood pressure) and methotrexate (used for rheumatism or cancer). Special care should be taken when taking either of these medicines with [TB326 trade name]. If you have kidney problems, your health care provider may want to give you a lower dose.

Do not take [TB326 trade name] at the same time as the following medicines. This is because they may stop your body from absorbing enough [TB326 trade name] to work properly:

Iron tablets (for anaemia), zinc supplements, magnesium or aluminium-containing antacids (for heartburn), didanosine, or sucralfate (for stomach ulcers).

Take your dose of these medicines at least 2 hours before or after [TB326 trade name].

Urine tests for opiates

Urine tests may show 'false-positive' results for strong painkillers called 'opiates' in people taking [TB326 trade name]. If your health care provider has prescribed a urine test, tell your health care provider you are taking [TB326 trade name].

Tuberculosis test

This medicine can cause a "false negative" result in some laboratory tests that look for the bacteria causing tuberculosis.

Taking [TB326 trade name] with food and drink

There are no restrictions on taking [TB326 trade name] with food and drink.

Pregnancy

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Since the safety of taking levofloxacin during pregnancy has not been investigated in humans, you should avoid becoming pregnant during treatment. You or your partner need to use a reliable form of barrier contraception (for example, a condom), or oral (pill) or other hormonal contraceptives (for example, implants, injection).

Breastfeeding

Since levofloxacin may pass over into the mother's milk and might hurt the development of your child's skeleton, you must not breastfeed while taking [TB326 trade name].

Driving and using machines

You may get side effects after taking this medicine, including feeling dizzy, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

3. How to take [TB326 trade name]

Always take [TB326 trade name] exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

Treatment of tuberculosis

For the treatment of TB, this medicine is taken together with other medicines. Your health care provider will tell you the right number of tablets of [TB326 trade name] to take, and how long to take them for. The dose depends on the weight of the person being treated. The usual doses in children are:

<i>Patient weight</i>	<i>Number of tablets daily</i>
3 to less than 5 kg	½ tablet
5 to less than 7 kg	1 tablet
7 to less than 10 kg	1½ tablets
10 to less than 16 kg	2 tablets
16 to less than 24 kg	3 tablets

For patients who weigh 24 kg or more or who are more than 15 years of age, your health care provider will recommend another medicine that contains more of the active substance.

Preventive treatment of tuberculosis

For prevention of tuberculosis, [TB326 trade name] is taken on its own once a day for 6 months. The number of [TB326 trade name] tablets taken daily depends on the age and weight of the person taking the medicine – your health care provider will tell you how many tablets to take.

The usual doses are:

<i>Person's weight</i>		<i>Number of tablets daily</i>
3 to less than 6 kg	<i>If less than 3 months of age</i>	½ tablet
	<i>3 months or age or more</i>	1 tablet
6 to less than 10 kg	<i>Less than 6 months of age</i>	1 tablet
	<i>6 months or age or more</i>	1½ tablets
10 to less than 15 kg		2 tablets
15 to less than 20 kg		2½ tablets
20 to less than 25 kg		3 tablets
25 to less than 30 kg		3½ tablets

For people who weigh 30 kg or more, or who are more than 15 years of age, the health care provider will recommend another medicine that contains more of the active substance.

Children with kidney problems

If you have a kidney disease, your health care provider may change the dose.

If you take too many [TB326 trade name] tablets

If you accidentally take more tablets than you should, tell a health care provider or get medical advice straight away. Take the medicine pack with you. This is so the health care provider knows what you have been taken. The following effects may happen: convulsive fits (seizures), feeling confused, dizzy, less conscious, having tremor and heart problems leading to uneven heart beats as well as feeling sick (nausea) or having stomach burning.

If you forget to take [TB326 trade name]

If you forget to take a dose, take the missed dose as soon as you remember on the same day. If you do not remember on the same day, take the normal dose on the next day. Do not take a double dose to make up for forgotten dose. If you are unsure about what to do, ask your health care provider.

If you stop taking [TB326 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB326 trade name] too soon, your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing the infection may become resistant to [TB326 trade name].

Taking this medicine

Make a mixture with the tablets in drinking water before taking the dose. Each tablet should be mixed with about 10 mL of water, up to a maximum of 50 mL.

1. Place the required volume of water in a small, clean cup or bowl and add the required number of tablets.
2. Stir gently until the tablets are fully mixed.
3. Drink the entire medicine mixture immediately.
4. Rinse the cup with a little additional water and drink this water.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB326 trade name] can cause side effects, but not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects from [TB326 trade name] and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform the health care provider of any change in your health.

Common side effects (may affect up to 1 in 10 people):

- Feeling and being sick (nausea, vomiting) and diarrhoea
- Increase in the level of some liver enzymes in the blood
- Headache, feeling dizzy
- Sleeping problems

Uncommon side effects (may affect up to 1 in 100 people):

- Itching and skin rash, severe itching or hives (urticaria), sweating too much (hyperhidrosis)
- Changes in the way things taste, loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation
- Blood tests may show abnormal results due to liver (bilirubin increased) or kidney (creatinine increased) problems
- Changes in the number of white blood cells shown up in the results of some blood tests
- General weakness
- Changes in the number of other bacteria or fungi that are normally found in the body, infection with a fungus called Candida, which may need to be treated

- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo)
- Shortness of breath (dyspnoea)
- Joint pain or muscle pain

Rare side effects (may affect up to 1 in 1,000 people):

- Pain and inflammation in your tendons or ligaments, which could lead to rupture. The Achilles tendon is affected most often
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.
- Red patches with or without blistering that develop within hours of intake of levofloxacin. After these have healed darker patches of skin are located at the site of the original disease. This usually comes back at the same site of the skin or mucous membrane upon another exposure to levofloxacin (post inflammatory residual hyperpigmentation)
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- Allergic reactions
- Painless swelling under the skin
- *Lowering* of your blood sugar levels (hypoglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes.
- Seeing or hearing things that are not there (hallucinations, paranoia), change in your opinion and thoughts (psychotic reactions)
- Tingly feeling in the hands and feet (paraesthesia) or trembling, fits
- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- State of mental confusion (delirium)
- Problems with hearing (tinnitus) or eyesight (blurred vision)
- Unusual fast beating of the heart (tachycardia), awareness of the heartbeat (palpitation) or low blood pressure (hypotension)
- Bruising and bleeding easily due to a lowering in the number of blood platelets (thrombocytopenia)
- Low number of white blood cells (called neutropenia)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system).
- Memory impairment
- Changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- Lowering of blood sugar levels leading to coma (hypoglycaemic coma).
- Fever

Other possible side effects, occurring at an unknown frequency, include:

- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. See also section 2.
- Loss of appetite, yellowing of the skin and eyes, dark-colored urine, stinging, or tender stomach

(abdomen). These may be the signs of liver problems which may include sudden liver failure.

- Lowering in red blood cells (anaemia): this can make the skin pale or yellow due to damage of the red blood cells; lowering in the number of all types of blood cells (pancytopenia)
- Fever, sore throat and a general feeling of being unwell that does not go away. This may be due to a lowering in the number of white blood cells (agranulocytosis).
- Loss of circulation (anaphylactic like shock)
- Watery diarrhoea which may have blood in it
- Increase of blood sugar levels (hyperglycaemia). This is important if you have diabetes.
- Changes in the way things smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Muscle twitches and jerks (myoclonus)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision
- Eye redness, pain and blurred vision (uveitis)
- Impairment or loss of hearing
- Life-threatening irregular heart rhythm including cardiac arrest, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
- Enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves. See also section 2.
- Difficulty breathing or wheezing (bronchospasm)
- Allergic lung reactions
- Pancreatitis
- Inflammation of the liver (hepatitis)
- Increased sensitivity of your child's skin to sun and ultraviolet light (photosensitivity)
- Darkening of the skin (hyperpigmentation)
- Inflammation of the vessels that carry blood around the body due to an allergic reaction (vasculitis)
- Inflammation of the tissue inside the mouth (stomatitis)
- Muscle rupture and muscle destruction (rhabdomyolysis)
- Joint redness and swelling (arthritis)
- Ligament and muscle rupture
- Pain, including pain in the back, chest and extremities
- Pain, numbness, tingling, burning, stabbing, muscle weakness in the feet or hands (peripheral sensory neuropathy)
- Decreased feeling in any area of the body, difficulty swallowing or breathing, difficulty using the arms or hands, legs or feet or difficulty walking. (peripheral sensory motor neuropathy)
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
- Persistent headache with or without blurred vision (benign intracranial hypertension)
- Risk of having suicidal thoughts or actions
- Mental disorder with extreme excitement and overactivity (mania)

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB326 trade name]

Keep this medicine out of the sight and reach of children.

Store below 30 °C in a dry place, protected from light.

Store tablets in the blisters or strips, in the provided carton.

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [TB326 trade name] contains

The active ingredient is levofloxacin (as hemihydrate) 100 mg

The other ingredients of [TB326 trade name] are: hydroxypropylcellulose, ethylcellulose, microcrystalline cellulose, crospovidone, sodium chloride, trisodium citrate dihydrate, citric acid monohydrate, aspartame, sucralose, peppermint flavour powder, orange flavour powder and magnesium stearate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB326 trade name] looks like and contents of the pack

[TB326 trade name] are off-white to pale yellow, capsule-shaped, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a break line on one side and are plain on the other side.

The break line can be used to divide the tablet into equal doses.

Blister packs:

Aluminium foil blister packs, each containing 10 tablets. Available in a carton of 100 tablets.

Strip packs:

Aluminium foil strip packs, each containing 10 tablets. Available in a carton of 100 tablets.

Supplier and Manufacturer

Supplier

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'For any information about this medicine, contact the supplier'.

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>