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

[TB237 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 [TB237 trade name] is and what it is used for

[TB237 trade name] is a medicine used 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.

[TB237 trade name] is also used on its own for the prevention of tuberculosis if you are at high risk of infection.

[TB237 trade name] contains the active substance levofloxacin and belongs to a group of antibiotics called fluoroquinolones.

2. What you need to know before you take [TB237 trade name]

Do not take [TB237 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 [TB237 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.

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 [TB237 trade name].

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

Warnings and precautions

Talk to your health care provider before taking [TB237 trade name]:

- If you are 60 years or older
- If you are using corticosteroids, sometimes called steroids (see "Other medicines and [TB237 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 [TB237 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 [TB237 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 [TB237 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 [TB237 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

- [TB237 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.
- [TB237 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 [TB237 trade name] and seek medical help immediately.
- Quinolone antibiotics, including [TB237 trade name], may cause convulsions. If this happens, stop taking [TB237 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 [TB237 trade name].
- You may experience mental health problems even when taking quinolone antibiotics, including [TB237 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 [TB237 trade name] and inform your health care provider immediately.
- You may develop diarrhoea whilst or after taking antibiotics including [TB237 trade name]. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking [TB237 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.
- [TB237 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 [TB237 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 [TB237 trade name].
- If you have diabetes and are using medicines to control your blood sugar, you should monitor your blood sugar levels carefully, as [TB237 trade name] in such cases may lower blood sugar levels.

Other medicines and [TB237 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

[TB237 trade name] can affect the way some other medicines work. Also, some medicines can affect the way

[TB237 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

[TB237 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 [TB237 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 [TB237 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 includes 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 [TB237 trade name]. If you have kidney problems, your health care provider may want to give you a lower dose.

Do not take [TB237 trade name] at the same time as the following medicines. This is because they may stop your body from absorbing enough [TB237 trade name]to work properly:

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

Take your dose of these medicines at least 2 hours before or after [TB237 trade name].

Urine tests for opiates

Urine tests may show ‘false-positive’ results for strong painkillers called ‘opiates’ in people taking [TB237 trade name]. If your health care provider has prescribed a urine test, tell your health care provider you are taking [TB237 trade name].

Tuberculosis test

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

Taking [TB237 trade name] with food and drink

There are no restrictions on taking [TB237 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 [TB237 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 [TB237 trade name]

Always take [TB237 trade name] exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with plenty of liquid
- The tablets may be taken during meals or at any time between meals
- Try to take the tablet(s) at approximately the same time each day.

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 to take, and how long to take them for. The dose depends on the weight of the person being treated.

Patients weighing 10 kg or more

The usual daily doses of [TB237 trade name] by weight in patients weighing 10 kg or more are:

Patient weight	***Number of tablets daily***
10 to less than 16 kg	1 tablet
16 to less than 24 kg	*See below*
24 to less than 30 kg	2 tablets
30 to less than 46 kg	3 tablets
46 to 70 kg or more	4 tablets

For patients weighing 16 to less than 24 kg, the dose is the equivalent of 1½ tablets. To give this dose you will need:

- 2 tablets of [TB237 trade name]
- drinking water
- a 10-mL oral syringe
- a container such as a bowl or a cup

1. Use the oral syringe to measure 10 mL drinking water into the container
2. Add 1 tablet of [TB237 trade name] and stir gently until the tablet breaks down and is fully mixed with the water. Make sure that the tablet breaks down completely
3. Use the oral syringe to measure 5 mL of the mixture and give it to the patient to take.
4. Then give the other tablet to the patient to take, with enough drinking water to wash it down.
5. Throw away any mixture remaining in the container.

Repeat these steps every time you need to give the medicine

Patients weighing less than 10 kg

For small children the dose of [TB237 trade name] may be less than one tablet. If your health care provider has selected this medicine for a child weighing less than 10 kg, you may need to make up a mixture with a [TB237 trade name] tablet and some water, as instructed by the health care provider.

You will need:

- 1 tablet of [TB237 trade name]
- drinking water
- a 10-mL oral syringe
- a container such as a bowl or a cup

1. Use the oral syringe to measure 10 mL drinking water into the container
2. Add 1 tablet of [TB237 trade name] and stir gently until the tablet breaks down and is fully mixed with the water. Make sure that the tablet breaks down completely
3. Use the oral syringe to give the right amount of the mixture, according to the child's weight:

Child weighing **3 to less than 5 kg**	give **2 mL** of the mixture
Child weighing **5 to less than 10 kg**	give **5 mL** of the mixture (child may be given half a tablet instead of making up mixture, if they are able to swallow tablets)

4. Throw away any mixture remaining in the bowl.

Repeat these steps every time you need to give the medicine.

Preventive treatment of tuberculosis

For prevention of tuberculosis, [TB237 trade name] is taken on its own once a day for 6 months. The number of [TB237 trade name] tablets taken daily depends on the weight of the person taking the medicine – your health care provider will tell you how many tablets to take.

Persons weighing 10 kg or more

The usual daily doses of [TB237 trade name] by weight in people weighing 10 kg or more are:

Patient weight	***Number of tablets daily***
10 to less than 15 kg	1 tablet
15 to less than 25 kg	*See below*
25 to less than 50 kg	2 tablets
50 kg or more	3 tablets

For people weighing 15 up to less than 25 kg the dose is the equivalent of 1½ tablets. To give this dose you will need:

- 2 tablets of [TB237 trade name]
- drinking water
- a 10-mL oral syringe
- a container such as a bowl or a cup

1. Use the oral syringe to measure 10 mL drinking water into the container
2. Add 1 tablet of [TB237 trade name] and stir gently until the tablet breaks down and is fully mixed with the water. Make sure that the tablet breaks down completely
3. Use the oral syringe to measure 5 mL of the mixture and give it to the person to take.
4. Then give the other tablet to the person to take, with enough drinking water to wash it down.
5. Throw any mixture remaining in the container.

Repeat these steps every time you need to give the medicine

Persons weighing less than 10 kg

For small children the dose of [TB237 trade name] may be less than one tablet. If your health care provider has selected this medicine for a child weighing less than 10 kg, you may need to make up a mixture with a [TB237 trade name] tablet and some water, as instructed by the health care provider.

You will need:

- 1 tablet of [TB237 trade name]

- drinking water
- a 10-mL oral syringe
- a container such as a bowl or a cup

1. Use the oral syringe to measure 10 mL drinking water into the container
2. Add 1 tablet of [TB237 trade name] and stir gently until the tablet breaks down and is fully mixed with the water. Make sure that the tablet breaks down completely
3. Use the oral syringe to give the right amount of the mixture, according to the child's age and weight:

Patient weight	***Age of child***	***How much to give***
3 to less than 6 kg	*If less than 3 months of age*	give **2.5 mL** of the mixture
	3 months or age or more	give **5 mL** of the mixture
6 to less than 10 kg	*If less than 6 months of age*	give **5 mL** of the mixture
	6 months or age or more	Child may be given **1 tablet daily** instead of a mixture

4. Throw away any mixture remaining in the bowl.

Repeat these steps every time you need to give the medicine.

If you have kidney problems

Your health care provider may need to give you a lower dose.

If you take more [TB237 trade name] than you should

If you accidentally take more tablets than you should, tell a health care provider or get other medical advice straight away. Take the medicine pack with you. This is so the health care provider knows what you have 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 [TB237 trade name]

If you forget to take your dose, you should take it as soon as you remember on the same day. If you do not remember on the same day, take your normal dose 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, ask your health care provider.

If you stop taking [TB237 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB237 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 your infection may become resistant to

[TB237 trade name].

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

4. Possible side effects

Like all medicines, [TB237 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 [TB237 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 (dyspnea)
- 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 haves 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 infammatory 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 [TB237 trade name]

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

Do not store above 30°C. Store in a dry place and protect from light.

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

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 [TB237 trade name] contains

- The active ingredient is levofloxacin 250 mg (as hemihydrate).
- The other ingredients of [TB237 trade name] are: croscarmellose sodium, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, hypromellose, iron oxide red, iron oxide yellow, macrogol, talc and titanium dioxide.

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

What [TB237 trade name] looks like and contents of the pack

The tablets are pale orange to pink, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have '250' debossed (stamped into) on one side and are plain on the other side.

The tablets are provided in:

Blister pack

Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 10x10 tablets.

HDPE bottle pack

Round, opaque white plastic (HDPE) containing 100 tablets. The bottle has a white childproof plastic (polypropylene) screw cap.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the supplier.

This leaflet was last revised in May 2025

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