

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

**LEVOFLOXACIN TRINITY 250** (Film coated tablets)

**LEVOFLOXACIN TRINITY 500** (Film coated tablets)

**Levofloxacin hemihydrate**

**Sugar free**

### Read all of this leaflet carefully before you start taking **LEVOFLOXACIN TRINITY**

- 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.
- **LEVOFLOXACIN TRINITY** 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 **LEVOFLOXACIN TRINITY** is and what it is used for
2. What you need to know before you take **LEVOFLOXACIN TRINITY**
3. How to take **LEVOFLOXACIN TRINITY**
4. Possible side effects
5. How to store **LEVOFLOXACIN TRINITY**
6. Contents of the pack and other information

#### 1. What **LEVOFLOXACIN TRINITY** is and what it is used for

Levofloxacin is a broad-spectrum bactericidal agent from the chemical group fluoroquinolone.

**LEVOFLOXACIN TRINITY** can be used in adults, in the treatment of the following bacterial infections:

- Acute exacerbations of chronic bronchitis.
- Pneumonia (community acquired).
- Sinusitis.
- Urinary tract infections and acute kidney inflammation.
- Skin and soft tissue infections.
- Stomach infection.

## **2. What you need to know before you take LEVOFLOXACIN TRINITY**

### **Do not take LEVOFLOXACIN TRINITY**

- if you are hypersensitive (allergic) to levofloxacin or any of the other ingredients of **LEVOFLOXACIN TRINITY** (listed in section 6),
- if you are epileptic,
- if you have a history of tendon disorders associated with previous fluoroquinolone use,
- if you are a child or an adolescent (under 18 years of age),
- if you are pregnant or breast-feeding,

as the use of **LEVOFLOXACIN TRINITY** are contraindicated in the above conditions.

### **Warnings and precautions**

Take special care with **LEVOFLOXACIN TRINITY**:

- If you are prone to seizures (fits), such as patients with pre-existing central nervous system lesions,
- If you are being treated with nonsteroidal anti-inflammatory medicines or
- If you are using medicines which treat epilepsy, such as theophylline.

- If you are being tested for tuberculosis as **LEVOFLOXACIN TRINITY** inhibit the growth of Mycobacterium tuberculosis and therefore may give false-negative results in the † diagnosis of tuberculosis.
- If you are exposed to ultraviolet (UVA) from sun beds, in order to prevent photosensitisation.
- If you are diagnosed with pseudomembranous colitis requiring the immediate stopping of **LEVOFLOXACIN TRINITY** and treatment with an appropriate specific antibiotic.
- When you experience a psychotic reaction. Psychotic reactions have been reported to occur already after the first dose. In the event of such adverse reactions, **LEVOFLOXACIN TRINITY** must be discontinued immediately, and you must contact your doctor immediately.
- When you have an allergic reaction. In the event of allergic reactions, **LEVOFLOXACIN TRINITY** must be discontinued immediately, and you must contact your doctor immediately.
- When your doctor has diagnosed you with tendonitis. Treatment with **LEVOFLOXACIN TRINITY** must be discontinued immediately and you must be immobilised and stay still. Tendon rupture may occur within 48 hours after starting treatment with **LEVOFLOXACIN TRINITY** and it may occur on both sides of the body.
- When you have been diagnosed with glucose-6-phosphate dehydrogenase deficiency. You may have to be monitored so that you do not have a blood reaction.
- When you have been diagnosed with a risk of QT prolongation (a heart condition) or you are on other medicines that may cause QT prolongation.
- When you have been diagnosed with myasthenia gravis. **LEVOFLOXACIN TRINITY** is not recommended if you have a known history of myasthenia gravis.

### **Children and adolescents**

Do not give **LEVOFLOXACIN TRINITY** to children and adolescents under the age of 18 years because it is unlikely to be safe.

### **Other medicines and LEVOFLOXACIN TRINITY**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LEVOFLOXACIN TRINITY** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

The absorption of **LEVOFLOXACIN TRINITY** is significantly reduced when administered with iron salts antacids and sucralfate. It is recommended that preparations containing iron salts, sucralfate, magnesium- or aluminium-containing antacids should not be taken 2 hours before or after **LEVOFLOXACIN TRINITY** tablet administration.

**LEVOFLOXACIN TRINITY** is known to inhibit metabolism and may interfere with the clearance of medicines, such as theophylline and nonsteroidal anti-inflammatory drugs (NSAIDs).

You should tell your doctor if you are taking medicines to treat:

- depression e.g., tricyclic antidepressants,
- mental disorders e.g., antipsychotics,
- cardiac disease like heart failure, myocardial infarction, bradycardia,
- electrolyte imbalance like hypokalaemia (low potassium levels), hypomagnesaemia (low

magnesium levels),

- diabetes e.g., glibenclamide,

as these medicines may interact with **LEVOFLOXACIN TRINITY**.

### **LEVOFLOXACIN TRINITY with food**

**LEVOFLOXACIN TRINITY** tablets may be taken on an empty stomach or with meals.

### **Pregnancy and Breastfeeding**

The use of **LEVOFLOXACIN TRINITY** during pregnancy and lactation is contra-indicated.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

### **Driving and using machines**

It is not always possible to predict to what extent **LEVOFLOXACIN TRINITY** 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 **LEVOFLOXACIN TRINITY** affects them.

The use of **LEVOFLOXACIN TRINITY** may alter the ability to drive or operate machinery as it may cause disturbances of the nervous system such as dizziness, visual and hearing disturbances, and disturbances of muscular co-ordination.

### **3. How to take LEVOFLOXACIN TRINITY**

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

Always take **LEVOFLOXACIN TRINITY** exactly as your doctor, or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

**LEVOFLOXACIN TRINITY** tablets should be swallowed whole, without crushing.

The usual dose to be taken is **LEVOFLOXACIN TRINITY** once or twice daily in a usual dose of 250 or 500 mg. The dosage will depend on the type of pathogen and the severity of the infection.

Renal impairment: The dosage will be adjusted.

No adjustment of dosage is required in the elderly or in patients with impaired liver function.

Your doctor will tell you how long your treatment with **LEVOFLOXACIN TRINITY** will last. Do not stop treatment early. If you have the impression that the effect of **LEVOFLOXACIN TRINITY** is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more LEVOFLOXACIN TRINITY than you should**

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

The symptoms that can be expected from an acute overdosage of **LEVOFLOXACIN TRINITY** are central nervous system symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures.

#### **If you forget to take LEVOFLOXACIN TRINITY**

If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Take your normal dose immediately and continue as prescribed. If you have forgotten to take several doses, contact your doctor without delay.

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

#### **4. Possible side effects**

**LEVOFLOXACIN TRINITY** can have side effects.

Not all side effects reported for **LEVOFLOXACIN TRINITY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LEVOFLOXACIN TRINITY**, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **LEVOFLOXACIN TRINITY**. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare.

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

- severe muscle and joint pain
- muscle weakness
- convulsions

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Shaking, changes in taste and smell
- Nausea, diarrhoea, stomach pain or discomfort, loss of appetite, vomiting

Less frequent side effects:

- Fungal overgrowth, increase in number of other organisms that have become resistant to the antibiotic
- Changes in the number of different types of blood cells in the blood (conditions known as eosinophilia, leukopenia, neutropenia, thrombocytopenia, agranulocytosis)
- Itchy skin, rash, itchy welts/hives, inflammation of blood vessels (vasculitis), swelling underneath the skin (angio-oedema), low blood pressure, severe allergic reactions such as anaphylactic-like shock or allergic type of lung inflammation (pneumonitis)
- Low blood-sugar levels (especially in patients with diabetes)
- Anxiety, depression, psychotic reactions (loss of contact with reality), nervousness, confusion, hallucinations
- Headache, dizziness, restlessness, drowsiness, sleeplessness, paraesthesia (a burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, but can also occur in other parts of the body), fits, disruptions in sight and hearing
- Bloody diarrhoea, which in some cases may be a symptom of serious inflammation in the large intestine (pseudomembranous colitis)
- Increase in liver enzymes, increase in bilirubin (breakdown product of red blood cells), hepatitis (inflammation of the liver), jaundice (yellowing of the skin, mucous membranes, and whites of the eye)
- Light sensitivity reactions, rash

- Joint stiffness, muscle aches and pain, tendon disorders e.g., tendonitis of the Achilles tendon, tendon tear, muscle weakness (especially in patients with myasthenia gravis)
- Kidney diseases called interstitial nephritis, crystalluria, kidney failure
- Physical weakness, fever

Frequency unknown:

- Change in blood cell counts (conditions called haemolytic anaemia, pancytopenia)
- Severe allergic skin reactions causing fluid filled blisters (such as Stevens Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, hypersensitivity vasculitis)
- Rhabdomyolysis (breakdown of muscle tissue)
- Local pain
- Increase level of creatinine in blood.

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, pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **LEVOFLOXACIN TRINITY**.

### **5. How to store LEVOFLOXACIN TRINITY**

Store all medicines out of the reach of children.

Store at or below 25 °C.

Store in the original package.

Do not store in bathrooms.

Do not use after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets)

## **6. Contents of the pack and other information**

### **What LEVOFLOXACIN TRINITY contains:**

The active substance is levofloxacin hemihydrate.

Each film coated tablet contains levofloxacin hemihydrate equivalent to levofloxacin 250 mg or 500 mg.

The other ingredients are cellulose microcrystalline, hypromellose, crospovidone, magnesium stearate, polyethylene glycol, polysorbate, titanium dioxide, ferric oxide red and ferric oxide yellow.

### **What LEVOFLOXACIN TRINITY looks like and contents of the pack**

**LEVOFLOXACIN TRINITY 250:** Light Pink coloured capsule shaped, film coated tablets debossed with break line on both sides, separating “2” & “50” on one side and “10” & “82” on other side.

**LEVOFLOXACIN TRINITY 500:** Brick red coloured capsule shaped, film coated tablets debossed with break line on both sides, separating “8” & “3” on one side and plain on other side.

100's: Printed unit carton containing 10 blister packs (composed of clear transparent PVC film

Trinity Pharma (Pty) Ltd.  
LEVOFLOXACIN TRINITY 250 / 500  
Levofloxacin 250 mg / 500 mg Film coated tablets

**Clinical approval date: 09 November 2022**

sealed with Aluminum foil) of 10 tablets each.

**Holder of Certificate of Registration**

TRINITY PHARMA (PTY) LTD

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Sandton,

2031

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**Registration number**

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**Access to the corresponding Professional Information**

[www.trinitypharma.co.za](http://www.trinitypharma.co.za)