

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

1. Scheduling Status:

S4

2. Name of the medicinal product:

TAVANIC 250 tablets

TAVANIC 500 tablets

TAVANIC I.V. 250 ready for use solution for intravenous infusion

TAVANIC I.V. 500 ready for use solution for intravenous infusion

3. What TAVANIC contains:

TAVANIC 250: Each tablet contains levofloxacin hemihydrate equivalent to 250mg of levofloxacin.

TAVANIC 500: Each tablet contains levofloxacin hemidrate equivalent to 500mg of levofloxacin. Each tablet also contains crospovidone, macrogol 8000, methylhydroxypropyl cellulose, microcrystalline cellulose, red ferric oxide, sodium stearyl fumarate, talc, titanium dioxide and yellow ferric oxide.

TAVANICI.V. 250: The active substance in each 50ml vial of solution for infusion is levofloxacin hemihydrate equivalent to 250mg (5mg per ml) levofloxacin.

TAVANIC I.V. 500: The active substance in each 100ml vial of solution for infusion is levofloxacin hemihydrate equivalent to 500mg (5mg per ml) levofloxacin.

The solution also contains sodium chloride, sodium hydroxide, hydrochloric acid and water for injection.

4. What TAVANIC is used for:

TAVANIC belongs to the class of medicines known as antibiotics. It is used to treat bacterial infections in many parts of the body. It works by killing bacteria or preventing their growth. Some infections which **TAVANIC** can be used to treat are: infections of the sinuses, chest infections in patients with long standing breathing difficulties, pneumonia, intra-abdominal (stomach and intestinal) infections, urinary tract infections (bladder and kidney) and skin infections.

5. Before you use TAVANIC:

Your doctor will consider the risks of taking **TAVANIC** before prescribing it for you.

The following will be considered:

Tell your doctor if you have ever had an allergic reaction to levofloxacin, any other quinolone antibiotic or to any substance listed under 'What **TAVANIC** contains'.

Tell your doctor if you suffer from epilepsy (fits or convulsions). Your risk of getting convulsions is increased when taking **TAVANIC**.

Tell your doctor if you have ever had tendon problems such as pain, inflammation or rupture of a tendon with treatment with an antibiotic for the fluoroquinolone class.

This is because there is a risk of getting similar problems with **TAVANIC**, including tendon rupture.

Tell your doctor if you are pregnant or breast feeding.

TAVANIC is only intended for adults and must not be given to children or growing teenagers. It could harm the cartilage of their growing bones.

Tell your doctor if you have had any problems with medicines in the past.

Take special care with TAVANIC:

- If you have a test for the diagnosis of tuberculosis, **TAVANIC** may give false-negative results.
- **TAVANIC** may cause some people to become dizzy, light-headed, drowsy or less alert than they are normally. Do not drive or operate machines if you are dizzy or not alert.
- When you use **TAVANIC** you may become more sensitive to sunlight than normally. Exposure to sunlight, even for brief periods may cause severe sunburn or skin rash, redness, itching or discolouration. Take precautions when exposed to sunlight and do not use a sun lamp or tanning bed.
- The risk of getting convulsions or fits may be increased if in the past you have experienced brain damage (such as stroke or severe brain injury) and are now treated with **TAVANIC**. (You should not be administered with **TAVANIC** if you suffer from epilepsy). Make sure your doctor knows about your medical history, so he can give you appropriate advice.
- Contact your doctor or healthcare professional immediately, if you develop watery diarrhoea, especially if the diarrhoea is persistent and/or bloody.

- You may develop tendinitis (inflammation of the tendon) with the use of **TAVANIC**.
- You may experience change in blood glucose levels (low blood sugar/ high blood sugar) if you are diabetic and are taking medication for the diabetes.

Taking other medicines with TAVANIC:

If you taking medicines on a regular basis, including complementary or traditional medicines, the use of **TAVANIC** with these medicines may cause undesirable interactions. Please consult your doctor for advice.

Tell your doctor if you are taking any of the following:

- Iron supplements or
- Antacids, magnesium- or aluminium-containing antacids or
- Sucralfate (e.g. Ulsanic) as these may interfere with the absorption of levofloxacin into the body;
- Inflammation or pain medicine (with fenbufen or similar medicines) or theophylline (used in some cough mixtures and for asthma) as the risk of convulsions may also be increased.
- Cimetidine used to treat ulcers
- Probenecid used to treat gout
- Medicines that affect the way your heart beats. This includes medicines used to treat depression (tricyclic antidepressants), to treat infections (macrolide antibiotics, erythromycin) and to treat abnormal heart rhythm (antiarrhythmics).
- Warfarin used to thin blood.

6. How to use / take TAVANIC:

The dose of **TAVANIC** is determined by the type and severity of the infection.

Always take **TAVANIC** tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

TAVANIC tablets may be taken during meals or any time between meals. Swallow the tablets without crushing with a full glass of water. They may be taken on an empty stomach or with meals. This medicine works best when there is a constant amount in the blood or urine. To help keep the amount constant, do not miss any doses. Also, it is best to take the doses at evenly spaced times day and night.

Your doctor will tell you how many **TAVANIC** tablets to take, at what time and for how long. Also, the number of doses you take each day, the time allowed between doses and the length of time you take the medicine depends on the medical problem for which you are taking levofloxacin. Most people need a dose of one or two tablets per day.

Your doctor or a nurse will administer **TAVANIC** by infusion into a vein. It will take at least 30 minutes for 250mg or 60 minutes for 500mg **TAVANIC** solution for infusion

Dosage in patients with normal kidney function: (creatinine clearance above 50ml/min):

Indication	Daily dosage regimen (according to severity)
Sinusitis	500mg once daily
Acute exacerbation of chronic bronchitis	500mg once daily

Community acquired pneumonia	500mg once or twice daily
Chronic bacterial prostatitis	500mg once daily
Complicated urinary tract infections	250mg ¹ once daily
Including pyelonephritis	
Skin and soft tissue infections	500mg twice daily
Intra-abdominal infections	500mg once daily

¹ consideration should be given to increasing the dose in cases of severe infection

Elderly patients and patients with impaired liver function (but normal kidney function) should receive the same dosage as normal adult.

If your kidney function is below normal your doctor will reduce the dose of **TAVANIC** accordingly.

The duration of treatment is determined according to your condition and your response to treatment.

If you miss a dose of **TAVANIC** tablets, take it as soon as you remember. However, if you don't remember until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take double doses.

What to do if you take too much TAVANIC:

Your doctor or nurse will ensure that you will receive the correct dose into the vein. An accidental overdose might result in central nervous system symptoms such as confusion, dizziness, reduced consciousness and convulsions. In the event of overdose, contact your nearest poison centre or hospital immediately.

7. Possible Side Effects:

TAVANIC can have side effects.

Check with your doctor immediately if any of the following side effects occur:

Very rare

You have an allergic reaction i.e. rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Shortness of breath

Also, check with your doctor as soon as possible if any of the following side effects

occur:

Rare

Watery diarrhoea which may have blood in it, possible with stomach cramps and a high fever; pain and inflammation of the tendons; fits

Very Rare

Burning, tingling, pain or numbness; loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine and abdominal pain, coma due to low blood sugar level

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

Common

Nausea, diarrhoea, local irritation and pain at site of injection

Uncommon

Itching, rash, loss of appetite, vomiting, stomach pain, indigestion, headache, dizziness, drowsiness, unable to sleep, a spinning feeling, general weakness

Rare

Depressed, anxious, mental problems, restlessness, confused, unusual fast beating of your heart, low blood pressure, joint and muscle pain

Very rare including isolated cases

- Increased sensitivity of your skin to sun and UV light, lowering of blood sugar levels symptoms: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat.(hypoglycaemia), high sugar (glucose) levels in the blood, problems with your hearing or eyesight or changes in the way things taste and smell, suicidal thoughts or actions, muscle weakness, liver and kidney problems, fever.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

8. Storage and disposal of TAVANIC

Store at or below 25 °C, in a dry place.

Protect from light. Keep product in the outer carton until required.

Once the single dose infusion vial has been opened, the infusion solution must be used within three hours, stored at 25 °C. Any unused infusion must be discarded.

The infusion vial can be refrigerated at 2 °C to 8 °C.

Do not use later than the date of expiry.

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

9. Presentation of TAVANIC

TAVANIC 250 (tablets): A carton containing blister pack of 3 or 5 tablets.

TAVANIC 500 (tablets): A carton containing one or more blister pack of

5 tablets each or one blister of 10 tablets

TAVANIC I.V. 250 (solution for infusion): 1 infusion vial of 50 ml per carton

TAVANIC I.V. 250 (solution for infusion): 1 infusion vial of 100ml per carton

10. Identification

TAVANIC 250 (tablets): Pale yellowish-white to reddish-white, oblong, biconvex film-coated tablets with a score line (13x6mm)

TAVANIC 500 (tablets): Pale yellowish-white to reddish-white, oblong, biconvex film-coated tablets with a score line (16 x 7.6mm)

TAVANIC I.V. 250 (solution for infusion): Greenish-yellow solution in clear, colourless glass vials a blue tear-off lid.

TAVANIC I.V. 500 (solution for infusion): Greenish-yellow solution in clear, colourless glass vials with a blue tear-off lid.

11. Registration number

TAVANIC 250: 32/20.1.1/0123

TAVANIC 500: 32/20.1.1/0124

TAVANIC I.V. 250: 34/20.1.1/0002

TAVANIC I.V. 500: 32/20.1.1/0125

12. Name and business address of the holder of the certificate of registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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13. Date of publication of the Patient Information Leaflet

18 April 2008