APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using TAVANIC I.V. 750.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TAVANIC I.V. 750 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.

SCHEDULING STATUS: S4

NAME OF THE MEDICINAL PRODUCT:

TAVANIC I.V. 750 (Ready for use solution for intravenous infusion)

WHAT TAVANIC I.V. 750 CONTAINS:

Each 150 ml vial of solution for infusion contains the active substance, levofloxacin hemihydrate equivalent to 750 mg (5 mg per ml) levofloxacin.

The solution also contains sodium chloride and water for injection.

WHAT TAVANIC I.V. 750 IS USED FOR:

TAVANIC I.V. 750 belongs to the class of antibiotics known as fluoroquinolone. It is used to treat bacterial infections. It works by killing bacteria or preventing their growth. Some infections for which TAVANIC I.V. 750 can be used to treat are: mild infections of the sinuses, mild chest infections in patients with chronic bronchitis and mild pneumonia.

BEFORE YOU USE TAVANIC I.V. 750:

Do not take TAVANIC I.V. 750:

- If you are allergic to TAVANIC I.V. 750 or any other quinolone antibiotic or any excipient listed under 'WHAT TAVANIC I.V. 750 CONTAINS'.
- If you suffer from epilepsy (fits or convulsions).
- If you have ever had tendon problems such as pain, inflammation or rupture of a tendon with treatment with an antibiotic of the fluoroquinolone class.
- If you are pregnant or breastfeeding.
- If you are under 18 years of age.

Take special care with TAVANIC I.V. 750:

- 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 I.V. 750.
- TAVANIC I.V. 750 must be stopped immediately, if you experience severe, persistent, bloody diarrhoea and your healthcare professional must be contacted.
- TAVANIC I.V. 750 must be used with caution in patients with kidney problems and patients with defects in glucose-6-phosphate dehydrogenase.
- If you have diabetes and you develop a low blood glucose (dizziness, sweating, etc.), you should stop taking TAVANIC I.V. 750 and contact your healthcare professional immediately.
- When you use TAVANIC I.V. 750 you may become more sensitive to sunlight than normal. 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.
- If you have a test for the diagnosis of tuberculosis, TAVANIC I.V. 750 may give false-negative results.
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Pregnancy and Breastfeeding

TAVANIC I.V. 750 must not be taken if you are pregnant or breastfeeding.

Driving and using machinery

TAVANIC I.V. 750 may cause some people to become dizzy, light-headed, drowsy or less alert than normal. Do not drive or operate machines if you are dizzy or not alert.

Taking other medicines with TAVANIC I.V. 750:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TAVANIC I.V. 750 together with these medicines may cause undesirable interactions. Please consult your doctor for advice.

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

- inflammation or pain medicine (NSAIDs) or theophylline (used for asthma) as the risk of convulsions may also be increased
- warfarin, as it may cause bleeding
- probenecid and cimetidine
- macrolide antibiotics such as erythromycin
- antidepressants
- antidysrhythmics (used for patients with a heart condition).

HOW TO USE/TAKE TAVANIC I.V. 750:

Your doctor or a nurse will administer TAVANIC I.V. 750 by infusion into the vein. It will take at least 90 minutes for TAVANIC I.V. 750 to be infused.

If your kidney function is below normal your doctor will reduce the dose.

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

POSSIBLE SIDE EFFECTS:

TAVANIC I.V. 750 can have side effects.

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 healthcare professional for advice.

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

Skin rash, itching or redness, tightness in the chest or breathing problems.

Also, check with your doctor as soon as possible if any of the following side effects occur: abdominal or stomach cramps or pain (severe); abdominal tenderness, agitation, blisters, confusion, diarrhoea (watery and severe) which may also be bloody; fever; hallucinations (seeing, hearing or feeling things that are not there); pain, inflammation, or swelling in calves of legs, shoulders, or hands; psychosis; sensation of skin burning; redness and swelling of skin, trembling.

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:

Abdominal or stomach pain or discomfort; change in sense of taste; diarrhoea; dizziness; drowsiness; headache; nausea; restlessness; unable to sleep; vomiting. Pain and redness at the infusion site. Low blood sugar levels.

STORAGE AND DISPOSAL OF TAVANIC I.V. 750:

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

Store at or below 25 °C. Protect from light.

Do not remove the vial from the carton until required for use.

Discard any unused solution in accordance with local requirements.

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

Do not dispose of unused medicine in drains or sewerage systems.

Return all unused medicine to your pharmacist.

PRESENTATION OF TAVANIC I.V. 750:

150 ml clear, colourless, Type 1 glass vial closed with a grey chlorobutyl rubber stopper and a silver (not painted) aluminium seal with a blue tear-off lid, packed in a paperboard carton.

IDENTIFICATION:

Greenish-yellow solution. Solution is sterile and practically free from visible particles.

REGISTRATION NUMBER:

43/20.1.1/0948

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill, Ext.1,

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