

PACKAGE LEAFLET: INFORMATION FOR THE USER

TAVANIC

250mg & 500mg Film-coated tablets

LEVOFLOXACIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TAVANIC is and what it is used for
2. Before you take TAVANIC
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4. Possible side effects
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1. WHAT TAVANIC IS AND WHAT IS IT USED FOR

The name of your medicine is TAVANIC

tablets. TAVANIC tablets contain a medicine called levofloxacin. This belongs to a group of medicines called antibiotics. Levofloxacin is a 'quinolone' antibiotic. It works by killing the bacteria that cause infections in your body.

TAVANIC tablets can be used to treat infections of the:

- Sinuses
- Lungs, in people with long-term breathing problems or pneumonia
- Urinary tract, including your kidneys or bladder
- Prostate gland, where you have a long lasting infection
- Skin and underneath the skin, including muscles. This is sometimes called 'soft tissue'

2. BEFORE YOU TAKE TAVANIC

Do not take this medicine and tell your doctor if:

- You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or any of the other ingredients of TAVANIC tablets (listed in Section 6 below)
Signs of an allergic reaction include: a 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 tendonitis that was related to treatment with a 'quinolone antibiotic'. A tendon is the cord that joins your muscle to your skeleton
- You are a child or a growing teenager
- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking TAVANIC tablets.

Take special care with TAVANIC tablets Check with your doctor or pharmacist before taking your medicine if:

- You are 65 years of age or older
- You are using corticosteroids, sometimes called steroids (see "Taking other medicines" below)
- You have ever had a fit (seizure)
- You have had damage to your brain due to a stroke or other brain injury
- You have kidney problems
- You have something known as 'glucose – 6 – phosphate dehydrogenase deficiency'. You are more likely to have serious problems with your blood when taking this medicine
- You have ever had mental health problems
- You have ever had heart problems
- You are diabetic
- You have ever had liver problems

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking TAVANIC tablets.

Taking other medicines

Please tell your doctor or pharmacist 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 TAVANIC tablets can affect the way some other medicines work. Also some medicines can affect the way TAVANIC tablets work.

In particular, tell your doctor if you are taking any of the following medicines. This is because it can increase the chance of you getting side effects, when taken with TAVANIC tablets:

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage of your tendons.
- Warfarin - used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Theophylline - used for breathing problems. You are more likely to have a fit (seizure) if taken with TAVANIC tablets
- Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with TAVANIC tablets
- 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 and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and Clarithromycin).
- Probenecid - used for gout, and cimetidine - used for ulcers and heartburn. Special care should be taken when taking either of these medicines with TAVANIC. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take TAVANIC tablets at the same time as the following medicines. This is because it can affect the way TAVANIC tablets work:

- Iron tablets (for anemia), magnesium or aluminum-containing antacids (for acid or heartburn) or sulcralfate (for stomach ulcers). See Section 3 "If you are already taking iron tablets, antacids or sulcralfate" below.

Urine tests for opiates

Urine tests may show 'false-positive' results for strong painkillers called 'opiates' in people taking TAVANIC tablets. If your doctor is due to take a urine test, tell them you are taking TAVANIC tablets.

Pregnancy and breast-feeding

Do not take this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may get side effects after taking this medicine, including 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 TAVANIC

Always take TAVANIC tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- The tablets may be taken during meals or at any time between meals

Protect your skin from sunlight

Keep out of direct sunlight while taking this medicine. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs
- Avoid sun beds

If you are already taking iron tablets, antacids or sulcralfate

- Do not take these medicines at the same time as TAVANIC. Take your dose at least 2 hours before or after TAVANIC tablets

How much to take

- Your doctor will decide on how many TAVANIC tablets you should take
- The dose will depend on the type of infection you have and where the infection is in your body
- The length of your treatment will depend on how serious your infection is
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor

Adults and the elderly

Sinuses

- Two tablets of TAVANIC 250 mg, once each day
- Or, one tablet of TAVANIC 500 mg, once each day

Lungs, in people with long-term breathing problems

- One or two tablets of TAVANIC 250 mg, once each day
- Or, 1/2 tablet or one tablet of TAVANIC 500 mg, once each day

Pneumonia

- Two tablets of TAVANIC 250 mg, once or twice each day
- Or, one tablet of TAVANIC 500 mg, once or twice each day

Urinary tract, including your kidneys or bladder

- One tablet of TAVANIC 250 mg, each day
- Or, 1/2 tablet of TAVANIC 500 mg, each day

Prostate gland

- Two tablets of TAVANIC 250 mg, once each day
- Or, one tablet of TAVANIC 500 mg, once each day

Skin and underneath the skin, including muscles

- One or two tablets of TAVANIC 250 mg, once or twice each day
- Or, ½ tablet or one tablet of TAVANIC 500 mg, once or twice each day

Adults with kidney problems

Your doctor may need to give you a lower dose

Children and Teenagers

This medicine must not be given to children or teenagers.

If you take more TAVANIC tablets than you should

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

If you forget to take TAVANIC tablets

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not double-up the next dose to make up for the missed dose.

If you stop taking TAVANIC tablets

Do not stop taking TAVANIC tablets just because you feel better. It is important that you complete the course of tablets that your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may return, your condition may get worse or the bacteria may become resistant to the medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TAVANIC can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Stop taking TAVANIC tablets and see a doctor or go to a hospital straight away if you notice the following side effect:

Very rare (affects less than 1 person in 10,000)

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue

Stop taking TAVANIC tablets and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Rare (affects less than 1 person in 1000)

- Watery diarrhoea which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem
- Pain and inflammation in your tendons. The Achilles tendon is affected most often and in some cases, the tendon could break
- Fits (convulsions)

Very rare (affects less than 1 person in 10,000)

- Burning, tingling, pain or numbness. These may be signs of something called 'neuropathy'

Other:

- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals

Stop taking TAVANIC tablets and see a doctor straight away (continued) :

- Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems

Tell your doctor if any of the following side effects gets serious or lasts longer than a few days:

Common (affects less than 1 person in 10)

- Feeling sick (nausea) and diarrhoea
- Increase in the level of some liver enzymes in your blood

Uncommon (affects less than 1 person in 100)

- Itching and skin rash
- Loss of appetite, stomach upset or indigestion (dyspepsia), being sick (vomiting) or pain in your stomach area, feeling bloated (flatulence) or constipation
- Headache, feeling dizzy, a spinning feeling (vertigo), feeling sleepy, sleeping problems or feeling nervous
- Blood tests may show unusual results due to liver or kidney 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 may increase, which may need to be treated

Rare (affects less than 1 person in 1,000)

- Tingly feeling in your hands and feet (paraesthesia) or trembling

- Feeling stressed (anxiety), depressed, mental problems, feeling restless (agitation) or feeling confused
- Severe itching or hives (called urticaria)

Very rare (affects less than 1 person in 10,000)

- Increased sensitivity of your skin to sun and ultraviolet light
- Lowering of your blood sugar levels (hypoglycaemia). This is important for people that have diabetes
- Problems with your hearing or eyesight or changes in the way things taste and smell
- Seeing or hearing things that are not there (hallucinations), change in your opinion and thoughts (psychotic reactions) with a chance of having suicidal thoughts or actions
- Loss of circulation (anaphylactic like shock)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system)
- Inflammation of the liver, changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- 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
- Fever and allergic lung reactions

Other side effects include:

- Lowering in red blood cells (anemia). This can make the skin pale or yellow due to damage of the red blood cells and lowering in the number of all types of blood cells
- Exaggerated immune response (hypersensitivity)
- Sweating too much (hyperhidrosis)
- Pain, including pain in the back, chest and extremities
- Problems moving and walking
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
- Inflammation of your tubes that carry blood around your body (vessels) due to an allergic reaction

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TAVANIC

Keep out of the reach and sight of children.

This medicine does not require any special storage conditions but it is best to keep TAVANIC tablets in the original strips and box in a dry place.

Do not use TAVANIC tablets after the expiry date (EXP) which is stated on the carton and foil.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What TAVANIC tablets contain

The active ingredient is levofloxacin. Each tablet of TAVANIC 250 mg tablets contains 250 mg of levofloxacin and each tablet of TAVANIC 500 mg tablets contains 500 mg of levofloxacin.

The other ingredients are:

- For the tablet core: crospovidone, hypromellose, microcrystalline cellulose and sodium stearyl fumarate

- For the tablet coating: hypromellose, titanium dioxide (E 171), talc, macrogol, yellow ferric oxide (E 172) and red ferric oxide (E 172)

What TAVANIC tablets look like and contents of the pack

TAVANIC tablets are film-coated tablets for oral use. The tablets are oblong and scored with a pale yellowish-white to reddish-white colour.

For TAVANIC 250 mg, the tablets are provided in pack sizes of 1, 3, 5, 7, 10, 50 and 200 tablets. For TAVANIC 500 mg, the tablets are provided in pack sizes of 1, 5, 7, 10, 50, 200 and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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These medicinal products are authorised in the Member States of the EEA under the following names:

TAVANIC 250 mg film-coated tablet TAVANIC 500 mg film-coated tablet

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.