

PATIENT COUNSELLING INFORMATION

^{Rx} Tinidazole & Ofloxacin Tablets

Tinicip-DS[®]

Read the entire leaflet carefully before you start taking this medicine:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

1. What is the fixed dose combination of Tinidazole & Ofloxacin Tablets and what is it used for?

Tinidazole is a synthetic antiprotozoal & antibacterial agent and Ofloxacin is a synthetic broad-spectrum antimicrobial agent. It is used to treat diarrhea of mixed infections in adult patients only.

You should ask your doctor if you are unsure why you have been given this medicine.

2. What you need to know before you take the fixed dose combination of Tinidazole & Ofloxacin Tablets?

Do not take the fixed dose combination of Tinidazole & Ofloxacin Tablets:

- If you are allergic to Tinidazole, Ofloxacin or any of the other ingredients of this medicine. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of lips, face, throat or tongue, wheezing.
- If you have previously had an allergic reaction to another quinolone antibiotic e.g. ciprofloxacin or norfloxacin.
- If you suffer from epilepsy or are at risk of fits.
- If you have a history of inflammation and swelling of the tendons (tendonitis) which can affect areas such as the wrist or the Achilles tendon after treatment with another quinolone antibiotic e.g. ciprofloxacin, norfloxacin, nadifloxacin, etc.

- If you suffer from or there is a family history of glucose-6-phosphate dehydrogenase deficiency (an inherited disorder that affects the red blood cells).
- If you are under the age of 18 years, or are still growing.
- You have a blood disorder or a history of blood disorders.
- Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor before taking the fixed dose combination of Tinidazole & Ofloxacin Tablets.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including the fixed dose combination of Tinidazole & Ofloxacin Tablets, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Talk to your doctor before taking the fixed dose combination of Tinidazole & Ofloxacin Tablets if any of the following apply:

- If you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- 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, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).
- If you feel sudden, severe pain in your abdomen, chest or back.
- You have or have ever had a history of mental illness.
- You have problems with your liver or kidneys.
- You have heart disease or problems with your heartbeat.
- 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.
- If you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are breastfeeding.
- You are taking other medicines that result in abnormal ECG changes.

- You have an illness of the nervous system called ‘myasthenia gravis’ (muscle weakness).
- If you are diabetic or suffer from low blood sugar.

During treatment

When taking this medicine

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

If you:

- experience a severe skin rash or allergic reaction, or
- develop severe diarrhoea, (which may be bloody) with stomach pain and fever, or
- notice pain, tenderness, or restricted movement of the tendons, or
- notice numbness or tingling in the hands and feet

Stop taking this medicine and talk to your doctor straight away.

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Ofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking the fixed dose combination of Tinidazole & Ofloxacin Tablets, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking the fixed dose combination of Tinidazole & Ofloxacin Tablets and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

Prolonged, disabling and potentially irreversible serious side effects
Fluoroquinolone/quinolone antibacterial medicines, including Ofloxacin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning

(paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders. If you experience any of these side effects after taking the fixed dose combination of Tinidazole & Ofloxacin Tablets, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

If you are not sure if any of the above applies to you, talk to your doctor before taking the fixed dose combination of Tinidazole & Ofloxacin Tablets.

Other medicines and the fixed dose combination of Tinidazole & Ofloxacin Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines.

You **must** tell your doctor if you are taking other medicines that can alter your heart rhythm:

- Medicines that belong to the group of anti-arrhythmics (e.g. Quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide),
- Tricyclic antidepressants, (e.g. Clomipramine, amitriptyline),
- Some antimicrobials (that belong to the group of macrolides e.g. Erythromycin, clarithromycin, azithromycin),
- Some antipsychotics used to treat mental health conditions such as schizophrenia and bipolar disorder.

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

- Medicines or dietary supplements that contain iron (for anaemia) or zinc.
- Sucralfate used for stomach ulcers.
- Antacids used for indigestion that contain magnesium or aluminium.
- Corticosteroids, used for treatment of inflammation and swelling or over-active immune system. These may increase the risk of you developing a tendon rupture.
- Painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or diclofenac, or theophylline, used to treat asthma or chronic obstructive pulmonary disease as these could make you more prone to fits if taken with Ofloxacin.
- Glibenclamide, a medicine to control your blood sugar, as the amount of these medicines in the blood may increase and have a greater effect.
- Drugs that may affect your kidney function e.g. cimetidine (used for stomach ulcers or indigestion), probenecid (used for gout) and methotrexate (used for rheumatism) as they can increase the level of Ofloxacin in the blood.

- Medicines to thin your blood, e.g. warfarin. Taking these with Ofloxacin can increase the time it takes for your blood to clot.
- If you are taking didanosine (a medicine used to treat HIV infections), you should not take the chewable, buffered tablets until at least two hours after taking Ofloxacin.
- Water tablets (diuretics) such as furosemide.

This medicine **should not** be taken within two hours of taking iron or zinc tablets, antacids, or sucralfate, as these medicines can stop Ofloxacin from working properly.

If you are due to have urine tests for porphyrin (a pigment in the blood), or for opiates (strong painkillers), tell your doctor or nurse you are taking this medicine.

Driving and using machines: Taking the fixed dose combination of Tinidazole & Ofloxacin Tablets may make you feel sleepy, dizzy or could affect your eyesight, problems with co-ordination or sensation (e.g. numbness or weakness). Do not drive or use machines until you know how this medicine affects you. Drinking alcohol may make these symptoms worse.

3. How to take the fixed dose combination of Tinidazole & Ofloxacin Tablets?

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- For oral use. You should swallow these tablets whole with water. Do not chew them.
- The tablets can be taken with or without food as instructed by your doctor.
- When taking the fixed dose combination of Tinidazole & Ofloxacin Tablets, avoid strong sunlight and do not use sun lamps or solaria as your skin may be more sensitive to light.
- If you are taking iron tablets (for anaemia), antacids (for indigestion or heartburn) or sucralfate (for stomach ulcers) or didanosine chewable or buffered tablets (for HIV), it is important not to take these two hours before or after taking Ofloxacin. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.
- When taking the fixed dose combination of Tinidazole & Ofloxacin Tablets, if your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- The length of your treatment will depend on how serious your infection is.

If you take more tablets of the fixed dose combination of Tinidazole & Ofloxacin than you should

If you take more tablets of the fixed dose combination of Tinidazole & Ofloxacin than you should then you may become confused and dizzy or lose consciousness, you may have a seizure or fit, and you may feel sick. Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

If you forget to take the fixed dose combination of Tinidazole & Ofloxacin Tablets

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking the fixed dose combination of Tinidazole & Ofloxacin Tablets

Your doctor will tell you how long you need to take your tablets for. Do not suddenly stop taking this medicine without talking to your doctor first. If you stop, your infection may get worse again. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the fixed dose combination of Tinidazole & Ofloxacin Tablets, tell your doctor or go to your nearest hospital casualty department straight away if you have any of the following serious side effects because you may need medical attention:

Tinidazole

Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips or tongue
- Fits or seizures

The common side effects (that may affect up to 1 in 10 people) are listed below:

- Nausea (feeling sick) or vomiting, loss of appetite, diarrhoea, stomach pain or cramps
- Headache
- Vertigo
- Skin rash or itching (especially affecting the whole body).

The frequency of the following side effects is not known (cannot be estimated from the available data):

- Numbness, tingling, pain or weakness in hands or feet
- Clumsiness or unsteadiness
- Fever or chills and painful ulcers in the mouth
- Sore or swollen mouth/tongue
- Redness of the face or neck
- Dizziness
- Tiredness
- Dark urine
- Tongue discolouration or unpleasant metallic taste.

Tinidazole can sometimes cause a temporary reduction in white blood cells which does not usually give you any symptoms.

Ofloxacin

Uncommon (may affect up to 1 in 100 people):

- Resistance of infection causing organisms to this treatment, (you may fail to respond to treatment)

Rare (may affect up to 1 in 1,000 people):

- You have an allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:
 - Severe skin rash.
 - Swelling of the face, lips, mouth, tongue or throat (angioedema).
 - Anaphylactic shock (sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing).
- Inflammation of the bowel, which may cause severe watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature.
- Swelling of the tendons with the following symptoms; pain, tenderness, sometimes restricted movement (tendonitis). This can lead to tendon rupture, especially of the large tendon at the back of the ankle (Achilles tendon). The risk

of this occurring is increased if you are also taking corticosteroids e.g. prednisolone.

- Numbness or tingling in the hands and feet or being very sensitive to touch, numbness or weakness of the arms and legs.
- Blurred, double or altered colour vision. If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Very rare (may affect up to 1 in 10,000 people):

- A condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal or an illness resulting from the destruction of red blood cells with the following symptoms; feeling tired, faint, dizzy, being short of breath when exercising and having pale skin. These may be signs of anaemia or haemolytic anaemia.
- Other blood disorders when the numbers of different types of cells in the blood may fall, which may cause fever, chills, sore throat, ulcers in the mouth and throat (leucopenia, agranulocytosis).
- Fits (seizures).
- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme).
- A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).
- Narrowing, blockage or leakage of blood vessels, in exceptional cases leading to severe skin reactions and death of areas of the skin.
- Severe kidney problems, which may result in your kidneys to stop working. Signs may include a rash, high temperature, general aches and pains, or blood in the urine.
- Hearing problems or hearing loss.
- Liver problems, such as inflammation of the liver (hepatitis) or blockage in the bile duct, that may cause your eyes or skin to go yellow (jaundice) or you may notice the following symptoms;
- Nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, light coloured bowel motions, dark coloured urine.

Not known (frequency cannot be estimated from the available data):

- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart).

- Severe depression or mental illness. Some people who are depressed think of harming or killing themselves.
- A serious reduction in all types of blood cells (pancytopenia), which may result from a failure of the bone marrow to produce these.
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens Johnson syndrome).
- Swelling of the lungs with the following symptoms; coughing, difficulty breathing, wheezing.
- Temporary paralysis or weakness of the muscles (rhabdomyolysis), disease of the muscles with the following symptoms; aching muscles, muscle tenderness or weakness, not caused by exercise.
- An attack of porphyria (a rare blood pigment disorder) in patients with this disease muscle or ligament rupture.
- Inflammation of the pancreas (pancreatitis) – you may have severe pain in the stomach and back.
- Loss of consciousness (coma), due to a severe reduction in blood sugar levels.
- Inflammation of the eye (uveitis).
- Skin redness with excessive scaling (exfoliative dermatitis).
- 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 which may include a fatal failure of the liver.

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

Uncommon (may affect up to 1 in 100 people)

- Feeling sick (nausea) or being sick (vomiting), diarrhoea or stomach pains.
- Irritated or burning eyes.
- Headaches, sleep disturbances including difficulty sleeping (insomnia).
- Feeling dizzy, having spinning sensations.
- Agitation, feeling restless.
- Cough and inflamed sore nose or throat (nasopharyngitis).
- Fungal infection.
- Skin rash or itching.

Rare (may affect up to 1 in 1,000 people)

- Loss of appetite.
- Fast heartbeat.

- Drowsiness.
- Feeling confused or anxious, nightmares, seeing, feeling or hearing things that are not there, depression and mental illness.
- Changes in or loss of your sense of taste or smell.
- Shortness of breath or wheezing.
- Changes in levels of liver enzymes or bilirubin, which may be seen in blood tests.
- Excessive sweating and hot flushes.
- Changes in kidney function shown in blood tests.
- Feeling faint, lightheaded or dizzy, which may be due to low blood pressure.
- Hives (urticaria).
- Rash with pimples.

Very rare (may affect up to 1 in 10,000 people)

- Uncontrolled movements, unsteadiness and shaking.
- Unusual bleeding or bruising more easily than normal (thrombocytopenia).
- Increase in some white blood cells (eosinophilia).
- Ringing in the ears (tinnitus).
- Joint and muscle pains.
- Skin rashes or eruptions, which may be caused by strong sunlight.
- Unusual purple discolouration under the skin, which may be due to bleeding or bruising due to leaky or damaged blood vessels.

Not known (frequency cannot be estimated from the available data)

- A red, scaly rash with bumps under the skin and blisters (exanthemous pustolosis).
- Muscular weakness, muscle tear.
- Feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar (glucose) levels especially in patients with diabetes or existing low blood sugar.
- An increase in blood sugar levels.
- Feeling of nervousness, tremor, unusual (involuntary) muscle movements, fainting.
- Digestive problems such as stomach upset (indigestion/heartburn), constipation, or wind.
- General pain, pains in your muscles and stiffness in the bones/joints (arthritis), feeling unwell (asthenia), or fever
- Persistent headache with or without blurred vision (benign intracranial hypertension).

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.

5. How to store the fixed dose combination of Tinidazole & Ofloxacin Tablets?

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store protected from light and moisture.

Keep out of reach of children.