

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Tarivid® 200 mg Film-coated Tablets

*Ofloxacin*

**Is this leaflet hard to see or read?**

**Phone 01 403 5600 for help**

**Read all of this 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 or pharmacist
- 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 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.

**In this leaflet:**

1. What Tarivid tablets are and what they are used for
2. Before you take Tarivid tablets
3. How to take Tarivid tablets
4. Possible side effects
5. How to store Tarivid tablets
6. Further information

#### **1. What Tarivid tablets are and what they are used for**

Tarivid tablets contain a medicine called ofloxacin. This belongs to a group of medicines called antibiotics. It works by killing bacteria that cause infections.

Tarivid tablets are used for infections of the:

- Urinary tract (bladder and kidney infection)
- Chest or lungs
- Genital tract infections in men and women (e.g. gonorrhoea, a sexually transmitted disease)
- Skin and soft tissue. Soft tissue is underneath the skin and includes muscle
- It could also be used to prevent infections in certain groups of patients

#### **2. Before you take Tarivid tablets**

**Do not take this medicine and tell your doctor if:**

- You are allergic (hypersensitive) to ofloxacin or any of the other ingredients of Tarivid 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 swelling of the tendons (called tendinitis) which can affect areas such as the wrist or the achilles tendon
- You have epilepsy or are at risk of fits
- You have a problem with your red blood cells known as 'glucose-6-dehydrogenase deficiency'
- You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' section below)
- You are under 18 years of age or are still growing
- You have received a transplantation
- You have a rare hereditary disorder that makes you unable to tolerate the sugars lactose (lactose intolerance) or glucose (glucose intolerance).

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 Tarivid tablets.

You should not take fluoroquinolone/quinolone antibacterial medicines, including Tarivid 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.

### **Warnings and Precautions**

Talk to your doctor or pharmacist before using Tarivid tablets if:

- You have liver or kidney problems
- You are elderly
- You have heart disease or problems with your heartbeat. Caution should be taken when using this kind of medicine, if 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 or you are taking other medicines that result in abnormal ECG changes (see section 'Other medicines and Tarivid tablets').
- You are taking medicines that can affect your heart (see section below on 'Other medicines and Tarivid tablets')
- You have low levels of potassium or magnesium in your blood
- You are taking a medicine to reduce blood clotting known as a Vitamin K Antagonist e.g. Warfarin. Your doctor will need to monitor you closely when taking both Vitamin K Antagonists and Tarivid tablets (see section 'Other medicines and Tarivid tablets')
- You have or have ever had any mental health problems
- You have diabetes
- If you have a condition called myasthenia gravis, which causes muscle weakness and excessive muscle fatigue.
- You have nerve problems (peripheral neuropathy)
- You have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- You have been diagnosed with leaking heart valves (heart valve regurgitation).
- You have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).

If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

### Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Tarivid, 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 Tarivid 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.

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Tarivid tablets. Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking your medicine and inform your doctor straight away (see Section 4).

Allergic (anaphylactic) reactions have been reported.

The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. If you experience an anaphylactic reaction, stop taking this medicine and contact your doctor straight away (see Section 4).

If you experience severe, persistent diarrhoea, possibly with blood in it, you may have pseudomembranous colitis (CDAD). CDAD can range from mild to life threatening in severity. If you suspect that you have symptoms of CDAD, stop taking this medicine and contact your doctor straight away (see Section 4).

This medicine may trigger fits (seizures). If you have a fit (seizure), stop taking this medicine and inform your doctor straight away (see Section 4). Patients with a history of epilepsy should not take Tarivid tablets.

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 Tarivid therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Tarivid tablets, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

If you develop thoughts of harming or killing yourself, stop taking this medicine and contact your doctor straight away (see Section 4).

If you experience difficulties with your eyesight while taking Tarivid tablets, contact your doctor immediately.

Tarivid tablets are not recommended if you have a suspected MRSA infection.

While being treated with Tarivid tablets, avoid strong sunlight and do not use sun lamps or solariums, as your skin may be more sensitive to light.

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 Tarivid tablets and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

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

### **Other medicines and Tarivid tablets**

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 Tarivid tablets and some other medicines can affect the way each other work.

### **In particular, tell your doctor if you are taking the following medicine:**

- Methotrexate, used for rheumatism or cancer
- Medicines that can alter your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol,

dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

**The following medicines can change the way Tarivid tablets work or Tarivid tablets may change the way some of these medicines work:**

- Medicines used to stop your blood from clotting (Vitamin K antagonists) e.g. warfarin
- Medicines used for high blood pressure
- Medicines that contain iron (for anaemia) or zinc
- Medicines that help put you to sleep (anaesthetics)
- Water tablets (diuretics) such as furosemide
- Antacids that contain magnesium or aluminium - used for indigestion
- Glibenclamide - used for diabetes
- Probenecid - used for gout
- Cimetidine - used for stomach ulcers or indigestion
- Sucralfate - used for stomach ulcers

**The following medicines, when taken with Tarivid tablets, can increase the chance of you getting side effects:**

- Other antibiotics (such as erythromycin, azithromycin or clarithromycin)
- Medicines for depression (such as amitriptyline, clomipramine or imipramine)
- Theophylline – used for breathing problems
- Medicines used to control your heartbeat (such as amiodarone, quinidine, procainamide, or disopyramide)
- Non steroidal anti-inflammatory drugs (NSAIDs) – used for pain relief and inflammation (such as ibuprofen, fenbufen, diclofenac or indometacin)
- Corticosteroids - used for inflammation

**Taking Tarivid tablets with food and drink**

Do not drink alcohol while taking Tarivid tablets. This is because it may make you feel dizzy or sleepy.

**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 breastfeed

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

**Driving and using machines**

You may feel sleepy or dizzy or have problems with your eyesight while taking this medicine. If this happens, do not drive or use any tools or machines.

**Important information about some of the ingredients of Tarivid tablets**

Tarivid tablets contain lactose. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking Tarivid tablets.

**3. How to take Tarivid tablets**

Always take Tarivid 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
- When taking Tarivid tablets, avoid strong sunlight and do not use sun lamps or solariums
- Medicines containing iron (for anaemia) antacids (for indigestion or heartburn) or sucralfate (for stomach ulcers) should be avoided for two hours before or after taking Tarivid Tablets
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor

### **When to take your medicine**

- The length of your treatment will depend on how serious your infection is
- Doses up to 400 mg are taken as a single dose in the morning
- Higher doses should be taken in two doses, one in the morning and one in the evening

### **How much to take**

- Your doctor will explain to you exactly how much Tarivid you will have to take as well as how often and for how long. This will depend on the type of infection you have

### **Kidney or liver problems**

If you have any kidney or liver problems you may be given a lower dose.

### **Children and Adolescents:**

This medicine should not be given to children or adolescents.

### **Elderly Patients:**

Blood tests to monitor kidney function should be performed in elderly patients taking Tarivid tablets and the dose of Tarivid may need to be adjusted accordingly.

The risk of tendinitis and tendon rupture is increased in patients over 60 years of age.

### **Urine Tests**

Taking Tarivid tablets may affect the results of some urine tests. If you are going to have a urine test, it is important to tell your doctor you are taking Tarivid tablets.

### **If you take more Tarivid tablets than you should**

If you take more Tarivid tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

This is so the doctor knows what you have taken. The following effects may happen: feeling confused or dizzy, seeing things that are not there, tremor, fast irregular heartbeat, loss of consciousness, fits, feeling sick or blood in your stools.

### **If you forget to take Tarivid tablets**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

### **If you stop taking Tarivid tablets**

Keep taking Tarivid tablets until your doctor tells you to stop. Do not stop taking Tarivid tablets just because you feel better. If you stop, your infection may get worse again.

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

## **4. Possible side effects**

Like all medicines, Tarivid tablets can cause side effects, although not everybody gets them.

### **Stop having Tarivid and tell a doctor or nurse straight away if you notice any of the following serious side effects - you may need urgent medical treatment:**

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

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.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

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

**Very Rare (affects less than 1 in 10,000 people)**

- Fits
  - Hearing problems or hearing loss
  - Liver problems that may cause your eyes or skin to go yellow (jaundice)
  - Severe skin rashes ( Erythema Multiforme, Toxic Epidermal Necrolysis) which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals.
- Symptoms may include flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking this medicine and inform your doctor straight away

- Skin rashes caused by strong sunlight
- Muscle weakness, joint and muscle pains
- Tendon rupture (achilles tendon) which may occur in both legs and within 48 hours of treatment
- Severe inflammation of the kidneys, which may result in your kidneys stopping working. Signs may include a rash, high temperature and general aches and pains
- Numbness or tingling in the hands and feet or being very sensitive to touch
- Problems with your coordination; you might experience spasms or irregular jerky movements
- A fever with chills and sweating - this may be signs of a blood problem called 'leukopenia'

**Rare (affects less than 1 in 1000 people)**

- An uneven or fast heartbeat, you may also feel faint
- Watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature
- Feeling faint, light headed or dizzy, due to low blood pressure
- Swelling or discomfort in your tendons, such as in the achilles tendon (tendinitis)
- Lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes.

**Not known (frequency unknown)**

- Lowering of your blood sugar levels (hypoglycaemia). This is important for people that have diabetes.
- High blood sugar levels
- Severe depression or mental illness. Some people who are depressed think of harming or killing themselves
- Abnormal, uncontrolled, involuntary movement such as fidgeting, wriggling or body swaying
- Weakness in the chest muscles that help you breathe and muscles that help you move parts of your body, including the arms and legs (Myasthenia gravis)
- 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 shortness of breath
- Severe abdominal pain (pancreatitis)
- Severe skin rashes (Stevens-Johnsons Syndrome) which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals. Symptoms may include flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking this medicine and inform your doctor straight away.
- Rare skin reaction characterised by the presence of pustules

- The onset of a drug rash - characterised by redness, bumps, blisters, hives, itching and sometimes peeling or pain
- Skin redness with extensive scaling (exfoliative dermatitis)
- A serious syndrome called Rhabdomyolysis which results from muscle injury
- Tear or rupture of the muscles or ligaments
- Inflammation of the eye (uveitis)
- 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
- A sudden fever with chills and sweating and a sore throat; this may be signs of a serious blood problem called 'agranulocytosis'
- Unusual bleeding and bruising, in which blood may be seen throughout the gums, nose or the skin. This may be signs of a 'bone marrow failure'

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

**Uncommon (affects less than 1 in 100 people)**

- Feeling or being sick, diarrhoea or stomach pains
- Cough and nasopharyngitis
- Headaches, sleeping problems, feeling dizzy or restless
- Skin rash or itching
- Eye irritation
- Fungal infection

**Rare (affects less than 1 in 1000 people)**

- Loss of appetite
- Delirium (acute confusional state)
- Feeling confused or anxious, nightmares, depression and mental illness, feeling drowsy, trembling, problems walking due to poor muscle control
- Changes in eyesight
- Changes in or loss of your sense of taste or smell
- Changes in levels of liver or kidney enzymes shown in blood tests
- A general feeling of being unwell
- Breathing problems
- Swelling of underneath the skin (angiodema)
- Hives or a rash with pustules
- Hot flushes or excessive sweating
- Abnormal pins and needles, tingling or numbness sensation
- Memory impairment
- Seeing or hearing things that are not there (hallucinations, paranoia), change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions

**Very Rare (affects less than 1 in 10,000 people)**

- Feeling tired, faint, dizzy and having pale skin. These could be signs of anaemia
- You may bruise more easily than usual. This could be because of a blood problem called 'thrombocytopenia'

**Not known (frequency unknown):**

- It is possible that Tarivid may trigger an attack of porphyria (a rare illness which affects the metabolism) in some patients.
- Indigestion, flatulence (passing wind), constipation
- Fever, pain (back, chest, limbs)
- Nervousness
- Tremor
- Loss of sense of taste
- Temporary loss of consciousness

- Cough or shortness of breath, caused by lung inflammation
- Inflammation of the mouth and lips
- Arthritis
- Abnormal physical weakness or lack of energy
- Persistent headache with or without blurred vision (benign intracranial hypertension)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRC Pharmacovigilance website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Tarivid tablets**

Keep out of reach and sight of children.

Do not use Tarivid tablets after the expiry date which is stated on the blister and carton after EXP. The expiry refers to the last day of that month. This medicinal product does not require any special storage conditions.

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 Tarivid tablets contain**

- Each 200mg tablet contains 200mg of the active substance, ofloxacin
- The other ingredients in the tablets are: Tablet Core: maize starch, lactose monohydrate, hypromellose, carmellose NS300, magnesium stearate; Tablet Coat: titanium dioxide (E171), talc, macrogol 8000, hypromellose.

#### **What Tarivid tablets look like and contents of the pack**

Tarivid tablets are yellowish-white, oblong, biconvex film-coated tablets with 'MXI' on one side of the score line and the Hoechst logo on the other. They are supplied in aluminium/PVC blisters in a pack size of 20 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

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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.

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