

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Tarivid IV 2 mg/ml
Solution for infusion
ofloxacin (as hydrochloride)

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 is and what it is used for
2. Before you have Tarivid
3. How Tarivid is given
4. Possible side effects
5. How to store Tarivid
6. Further information

1. What Tarivid is and what it is used for

The name of your medicine is Tarivid IV 2 mg/ml Solution for Infusion (called Tarivid throughout this leaflet). Tarivid infusion contains a medicine called ofloxacin. This belongs to a group of medicines called antibiotics. It works by killing bacteria that cause infections.

Tarivid is indicated in adults for the treatment of the following bacterial infections:

- urinary tract infections (kidney infection)
- genital tract infections in men and women including cases where these infections spreads into blood stream
- Chest or lungs
- Skin and soft tissue. Soft tissue is underneath the skin and includes muscle

2. Before you have Tarivid

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to ofloxacin or any of the other ingredients of Tarivid (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

Do not have this medicine if any of the above apply to you. If you are not sure, talk to your nurse, doctor or pharmacist before having Tarivid.

You should not take fluoroquinolone/quinolone antibacterial medicines, including Tarivid IV, 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 if:

- You have liver or kidney problems
 - You are elderly
 - You have heart disease or problems with your heartbeat
 - You are taking medicines that can affect your heart or lower your blood pressure (see section below on 'Other medicines and Tarivid')
 - 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 (see section 'Other medicines and Tarivid').
 - You have or have ever had any mental health problems
 - You have porphyria (a rare illness which affects the metabolism)
 - You are going to have an operation under general anaesthetic whilst being treated with Tarivid
 - You have a condition called myasthenia gravis, which causes muscle weakness and excessive muscle fatigue.
 - You have diabetes
 - You have received a transplantation
 - 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 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, go immediately to an emergency room.

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 IV, 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.

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').

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Tarivid. 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 pseudo-membranous 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.

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 IV, 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, contact your doctor immediately.

Tarivid is not recommended if you have a suspected MRSA infection.

Cases of liver injury have been reported especially in patients with existing liver problems. While being treated with Tarivid, 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 IV 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, pharmacist or nurse before having Tarivid.

Other medicines and Tarivid

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 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 works or Tarivid 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 or medicines that lower blood pressure
- Medicines that help put you to sleep (anaesthetics)
- Water tablets (diuretics) such as furosemide
- Glibenclamide – used for diabetes
- Probenecid – used for gout
- Cimetidine – used for stomach ulcers or indigestion

The following medicines, when taken with Tarivid, 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

Having Tarivid with food and drink

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

Pregnancy and breast-feeding

Do not have 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 having this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Tarivid

This medicinal product contains 354 mg of sodium per 100 ml dose. This is equivalent to 18% of the recommended maximum daily dietary intake of sodium for an adult.

The maximum recommended daily dose of this medicinal product contains 1416 mg sodium (found in table salt). This is equivalent to 71% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Tarivid IV on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How Tarivid is given

Having this medicine

- Your doctor or nurse will normally give you Tarivid. This is because it needs to be given as a slow infusion (drip) into a vein
 - When having Tarivid, avoid strong sunlight and do not use sun lamps or solariums
- If you are not sure why you are receiving Tarivid or have any questions about how much Tarivid is being given to you, speak to your doctor, pharmacist or nurse

How long you will have Tarivid

- The length of your treatment will depend on how serious your infection is
- The medicine is usually given for 7 to 10 days and treatment should not be longer than 2 months
- Once your illness has improved your doctor may change your medicine to Tarivid tablets

How much will be given to you

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 and how bad it is.

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.

If you have more Tarivid than you should

Your doctor will carefully calculate how much Tarivid you should get. Therefore it is unlikely your doctor, nurse or pharmacist will give you too much of this medicine. But, if you think that you have been given too much or too little Tarivid, tell your doctor, nurse or pharmacist. The following effects may happen: confusion, feeling dizzy, seeing things that are not there, tremor, fast irregular heartbeat, loss of consciousness, convulsion, seizures (fits), nausea or bleeding in stools.

If you forget to have Tarivid

Your doctor or nurse will have instructions about when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose, then talk to your doctor or nurse.

If you stop having Tarivid

Keep having Tarivid until your doctor tells you to stop. Do not stop having Tarivid just because you feel better. It is important for you to keep having Tarivid injections until your doctor decides to stop them. If you stop, your infection may get worse again.

Elderly Patients:

Blood tests to monitor kidney function should be performed in elderly patients taking Tarivid 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

Having Tarivid 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 having Tarivid.

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

4. Possible side effects

Like all medicines, Tarivid 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.

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
- The onset of an irregular, fast heartbeat and a drop in blood pressure may occur during a Tarivid infusion, which in very rare cases can be severe
- 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:

Common (affects less than 1 in 10 people)

- Pain, redness or swelling on the vein or area you have been injected with Tarivid

Uncommon (affects less than 1 in 100 people)

- Feeling or being sick, diarrhoea or stomach pains
- Cough, 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
- 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):

- Indigestion, flatulence (passing wind), constipation
- Fever, pain (back, chest, limbs)
- It is possible that Tarivid may trigger an attack of porphyria (a rare illness which affects the metabolism) in some patients.
- 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 HPRA Pharmacovigilance. Website: www.hpra.ie

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

5. How to store Tarivid

Keep out of reach and sight of children.

Do not store above 30°C. Store in the original container, protected from light.

Do not use Tarivid IV 2mg/ml Solution for Infusion if you notice that the solution is not a clear, greenish-yellow solution and/or has particles in it.

Once the infusion bottle has been opened the solution should be used immediately. Discard any unused contents.

Tarivid IV 2mg/ml Solution for Infusion is intended for single use only.

Do not use Tarivid after the expiry date, which is stated on the label and carton after EXP. The expiry refers to the last day of that month.

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 contains

- Each vial of 100ml contains 200mg Ofloxacin equivalent to 220mg of Ofloxacin hydrochloride (2mg/ml Ofloxacin).
- The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections

What Tarivid looks like and contents of the pack

Tarivid IV 2 mg/ml Solution for Infusion is a clear greenish-yellow solution in 1 vial of 100 ml glass bottles with grey chlorobutyl rubber closures and aluminium caps.

Marketing Authorisation Holder and Manufacturer

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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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