

- 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.

Rare (affects less than 1 in 1000 people)

- Numbness or tingling in the hands and feet or being very sensitive to touch

Frequency Unknown

- 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)
- Indigestion, flatulence (passing wind), constipation
- Fever, pain (back, chest, limbs)
- Severe abdominal pain (pancreatitis)
- Impaired hearing
- Inflammation of the eye (uveitis)
- Liver problems
- Problems with eye sight
- Skin redness with extensive 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 (affects less than 1 in 100 people)

- Feeling or being sick, diarrhoea or stomach pains

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- Headaches, sleeping problems, feeling dizzy or restless
- Skin rash or itching

Rare (affects less than 1 in 1000 people)

- Loss of appetite
- Feeling confused or anxious, nightmares, seeing things that are not there, 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 enzymes shown in blood tests
- A general feeling of being unwell
- Pain, redness or swelling on the vein or area you have been injected with Tarivid

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 feel weak, bruise more easily and get more infections than usual. This could be because of a blood problem called 'pancytopenia'
- Cough or shortness of breath, caused by lung inflammation

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

- Persistent headache with or without blurred vision (benign intracranial hypertension)

It is possible that Tarivid may trigger an attack of porphyria (a rare illness which affects the metabolism) in some patients.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tarivid

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it. Store in the original carton in order to protect from light.

Do not use Tarivid after the expiry date, which is stated on the label. 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. Contents of the pack and other information

What Tarivid contains

- Each 1ml contains 2mg of the active substance, ofloxacin
- The other ingredients are sodium chloride, hydrochloric acid and water for injections

What Tarivid looks like and contents of the pack

Tarivid® is a clear greenish-yellow solution in glass vials with grey chlorobutyl rubber closures and aluminium caps containing either 50ml, 100ml or 200ml. Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

Sanofi-Aventis Deutschland GmbH
Bruningstrasse 50, D-65926 Frankfurt am Main, Germany

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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PACKAGE LEAFLET: INFORMATION FOR THE USER

Tarivid® 2mg/ml Solution for Infusion

ofloxacin

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Is this leaflet hard to see or read? Phone 0845 372 7101 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.

What is in this leaflet

1. What Tarivid is and what it is used for
2. What you need to know before you take Tarivid
3. How Tarivid is given
4. Possible side effects
5. How to store Tarivid
6. Contents of the pack and other information

1. What Tarivid is and what it is used for



The name of your medicine is Tarivid 2mg/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 (kidneys 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. What you need to know before you take 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)
- × 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.



Warnings and Precautions

Before taking this medicine

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



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Talk to your doctor or pharmacist before using Tarivid if:

- ▲ You have liver or kidney problems
- ▲ You have heart disease or problems with your heartbeat
- ▲ You have received a transplantation
- ▲ You have nerve problems (peripheral neuropathy)
- ▲ You are taking medicines that can affect your heart or lower your blood pressure (see section 'Taking other medicines')
- ▲ You were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart)
- ▲ You have a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
- ▲ You have a very slow heart rhythm (called 'bradycardia')
- ▲ You have a weak heart (heart failure)
- ▲ You have a history of heart attack (myocardial infarction)
- ▲ You are female or elderly
- ▲ You are taking other medicines that result in abnormal ECG changes (see section 'Taking other medicines')
- ▲ 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 suffer from a condition called 'myasthenia gravis', which causes muscle weakness and excessive muscle fatigue
- ▲ You have been told by your doctor that you cannot tolerate some sugars.
- ▲ 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)

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- ▲ 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.

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

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. If you experience pain in your fingers or toes whilst being treated with Tarivid, tell your doctor or nurse immediately.

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

When taking this medicine

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.

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At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Tarivid, 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 Tarivid 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 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, 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.



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

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
- 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
- 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, diclofenac or indometacin)
- Corticosteroids – used for inflammation
- Antipsychotics – used to treat psychiatric disorders such as schizophrenia and bipolar disorder

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 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 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

Tarivid infusion contains sodium. There is 354mg of sodium per 2mg of infusion. This may be harmful to people on a low sodium or 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 taking Tarivid, if your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately
 - When having Tarivid, avoid strong sunlight and do not use sun lamps or solaria
- 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
- 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 decide on how much Tarivid you should have
- The dose will depend on the type of infection you have

The usual dose for adults, including the elderly, is between 200mg and 800mg each day.

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, 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.

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.

Tell a nurse or doctor straight away if you have any of the following serious side effects:

- 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 (affects less than 1 in 10,000 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
- Fits
- Hearing problems or hearing loss
- Liver problems that may cause your eyes or skin to go yellow (jaundice)
- Severe skin rashes (Stevens-Johnson Syndrome, 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
- Feeling faint, light-headed or dizzy, due to low blood pressure
- Muscle weakness, joint and muscle pains
- Feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar levels
- Feeling thirsty and passing water more often than usual. This could be due to a rise in blood sugar levels
- Swelling or discomfort in your tendons, such as in the achilles tendon
- 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
- Severe depression or mental illness. Some people who are depressed think of harming or killing themselves

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