

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

**Tarivid® 200 mg Tablets**

**Tarivid® 400 mg Tablets**

ofloxacin

**sanofi aventis**



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

**Phone 01483  
505515 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
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**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:

- Kidneys or bladder (urinary tract)
- Chest or lungs
- Male or female sex organs (genital tract). This includes gonorrhoea which is a sexually transmitted infection that can affect both men and women
- Skin and soft tissue. Soft tissue is underneath the skin and includes muscle

**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

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.





**Take special care with Tarivid tablets. Caution should be taken when using this kind of medicine.**

**Check with your doctor or pharmacist before taking your medicine if:**

- ▲ You have liver or kidney problems
- ▲ You have heart disease or problems with your heartbeat
- ▲ You are taking medicines that can affect your heart (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 suffer from a condition called 'myasthenia gravis' (muscle weakness)
- ▲ You have been told by your doctor that you can not tolerate some sugars.

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

Other medicines that can alter your heart rhythm:

- Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amioderone, 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
- 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, diclofenac or indometacin)
- Corticosteroids - used for inflammation
- Antipsychotics - used to treat psychiatric disorders such as schizophrenia and bipolar disorder.

**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 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 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 cannot 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 solaria
- 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
- The medicine is usually taken for 5 to 10 days and treatment should not be longer than 2 months
- 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 decide on how many Tarivid tablets you should take
- The dose will depend on the type of infection you have

The usual dose for adults, including the elderly, is between 200 mg and 800 mg each day. The dose depends on the location and type of infection:

- **Kidney or bladder infections (urinary tract):**  
200 to 800 mg each day
- **Chest or lung:**  
400 to 800 mg each day
- **Male or female sex organ infections (genital tract):**  
400 mg each day
- **Gonorrhoea**  
a single dose of 400 mg
- **Skin and soft tissue infections:**  
400 to 800 mg each day

### 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.

### 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, 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 taking Tarivid tablets and see a doctor or go to a hospital straight away if:

- 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 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)

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

**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)

**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
- 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

**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'
- Cough or shortness of breath, caused by lung inflammation

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

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.



## 5 How to store Tarivid tablets

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Tarivid tablets after the expiry date which is stated on the label. The expiry refers to the last day of that month. Keep the blister strip in the outer carton in order to protect from moisture.

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
- Each 400mg tablet contains 400mg of the active substance, ofloxacin
- The other ingredients in the tablets are lactose, maize starch, sodium starch glycollate (400mg only), hypromellose, carmellose (200mg only), magnesium stearate, hypromellose, macrogol 8000, talc, titanium dioxide (E171), yellow ferric oxide (E172 - 400mg only), purified water

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

Tarivid 200mg tablets are oblong pale yellowish-white tablets. They are marked on each face with 'MXI' on one side of the score-line and the Hoechst logo on the other. They are supplied in aluminium/PVC blisters in pack sizes of 10, 20 and 100 tablets.

Tarivid 400mg tablets are oblong pale yellow tablets. They are marked on each face with 'MXL' on one side of the score-line and the Hoechst logo on the other. They are supplied in aluminium/PVC blisters in pack sizes of 5, 10 and 50 tablets.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Tel: 01483 505515

Fax: 01483 535432

email: [uk-medicalinformation@sanofi-aventis.com](mailto:uk-medicalinformation@sanofi-aventis.com)

#### Manufacturer

Sanofi Winthrop Industrie  
56, route de Choisy au Bac,  
60205 Compiègne, France

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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