

PATIENT COUNSELLING INFORMATION**Rx Ciprofloxacin & Tinidazole Tablets****CITIZOL™****Read the entire leaflet carefully before you start taking this medicine:**

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others, 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 Citizol™ and what is it used for?

Citizol™ tablets contain Ciprofloxacin and Tinidazole. Ciprofloxacin is a synthetic broad-spectrum antimicrobial agent and Tinidazole is a synthetic antiprotozoal & antibacterial agent. It is used to treat diarrhoea 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 Citizol™?**Before you take Citizol™, talk to your doctor:**

- If you are allergic to Ciprofloxacin, Tinidazole 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 a blood disorder or a history of blood disorders.
- If you have central nervous system (CNS) disease, including epilepsy.
- If you are in the first 13 weeks of pregnancy or trying to become pregnant or you are breast-feeding.

Warnings and precautions:

Talk to your doctor before taking Citizol™ Tablets:

- If during therapy you develop abnormal neurological signs (such as, dizziness, vertigo, difficulty in controlling movements).
- If you suffer from epilepsy or are at risk of fits.
- If you have ever had kidney problems because your treatment may need to be adjusted.
- If you have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin.
- If you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin.
- If you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- If you have heart problems, 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.

Contact your doctor immediately, if any of the following occurs while taking Citizol™ Tablets.

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angio-oedema). Even with the first dose, there is a small chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up.
- Pain and swelling in the joints and tendinitis may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Citizol™ Tablets therapy. At the first sign of any pain or

inflammation, stop taking Citizol™ Tablets and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture.

- If you suffer from epilepsy or other neurological conditions such as cerebral ischemia or stroke, you may experience side effects associated with the central nervous system.
- You may experience psychiatric reactions the first time you take Citizol™ Tablets. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Citizol™ Tablets. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness.
- Hypoglycemia has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
- Diarrhoea may develop while you are taking antibiotics, including Citizol™ Tablets, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Citizol™ Tablets immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking Citizol™ Tablets if you have to provide a blood or urine sample.
- If you suffer from kidney problems, tell the doctor because your dose may need to be adjusted.
- If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, stop taking Citizol™ Tablets and contact your doctor immediately.
- Citizol™ Tablets may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking Citizol™ Tablets. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Other medicines and Citizol™:

Please tell your doctor if you are taking or have recently taken any other medicines, including those medicines obtained without a prescription.

- If you are currently taking blood thinners such as warfarin to prevent blood clots as your doctor may wish to monitor you more closely.

Citizol™ Tablets can increase the level of the following substances in the blood:

Do not take Citizol™ together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness.

The following medicines are known to interact with Citizol™ in your body. Taking Citizol™ Tablets together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood)
- Theophylline (for breathing problems)
- Phenytoin (used to treat epilepsy)
- Ropinirole (for Parkinson's disease)
- Cyclosporin (used to treat psoriasis, dermatitis, rheumatoid arthritis and in organ transplantation)
- Probenecid (used to prevent gout)
- Metoclopramide (used to treat nausea and vomiting (feeling/being sick) and migraine)
- Methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- Tizanidine (for muscle spasticity in multiple sclerosis)
- Clozapine (an antipsychotic)
- Olanzapine (an antipsychotic)

- Other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, amiodarone, sotalol, tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Citizol™ may increase the levels of the following medicines in your blood:

- Pentoxifylline (for circulatory disorders)
- Caffeine
- Duloxetine (for depression, diabetic nerve damage or incontinence)
- Lidocaine (for heart conditions or anesthetic use)
- Sildenafil (e.g. for erectile dysfunction)

Some medicines reduce the effect of Citizol™. Tell your doctor if you take or wish to take:

- Antacids, Metal cations, Multivitamins
- Omeprazole
- Mineral supplements
- Sucralfate
- A polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate)
- Medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take Citizol™ about two hours before or no sooner than four hours after them.

Taking Citizol™ with food and drink

Unless you take Citizol™ during meals, do not eat or drink any dairy products (such as milk or yogurt) or drinks with added calcium when you take the tablets. These can affect the absorption of Ciprofloxacin and so you should take your tablets either 1 to 2 hours before or at least 4 hours after you have such products.

You should not drink wine, beer or spirits during treatment and for 3 days after stopping treatment with this medicine. The combination may cause flushing, stomach cramps, vomiting (being sick) and palpitations (pounding heart).

Pregnancy

It is preferable to avoid the use of Citizol™ during pregnancy. You should not take this medicine if you are in the first 13 weeks of pregnancy. Tell your doctor if you are pregnant or planning to become pregnant.

Breast-feeding

Do not take Citizol™ tablets during breast feeding because Ciprofloxacin is excreted in breast milk and can be harmful for your child.

If you stop breast-feeding during treatment you should not start again until at least 3 days after stopping.

Ask your doctor for advice before taking any other medicine.

Driving and using machines

Do not drive or use machinery if this medicine makes you feel drowsy or gives you problems with co-ordination or sensation, Citizol™ may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Citizol™ before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

3. How to take Citizol™?

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

- Citizol™ should always be taken with plenty of water, as this will help to prevent the formation of tiny crystals in your urine (crystalluria). Swallow the tablets whole, do not chew the tablets.
- You can take Citizol™ at meal times or between meals. Any calcium you take as a part of a meal will not seriously affect uptake. However, do not take the tablets with dairy products such as milk or yogurt or with fortified fruit juices (eg. Calcium-fortified orange juice).
- Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted. The treatment usually lasts from 5 to 21 days, but may take longer for severe infections.

- Your dose will be dependent on the type and severity of your infection, your age, weight and kidney function. Your doctor will choose the best dose for you.

If you take more tablets of Citizol™ than you should

If you take more tablets of Citizol™ than you should, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

If you forget to take Citizol™

If you forget to take this medicine take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose. Be sure to complete your course of treatment.

If you stop taking the Citizol™

It is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop taking this medicine too soon your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antibiotic.

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

4. Possible side effects

Like all medicines, Citizol™ can cause side-effects, although not everybody gets them.

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.

Ciprofloxacin

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. If this happens to you, stop taking the tablets immediately and seek medical help

if any of the following occur:

- Muscle pain and/or weakness, inflammation of the joints and joint pain, increased muscle tone and cramping, inflammation of the tendons or tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon). If you experience this, rest the affected limb, discontinue treatment and seek medical advice immediately.
- Unusual feelings of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy).
- Infection with symptoms such as fever and serious deterioration of your general condition (there may be a dangerous drop in a type of white blood cells (agranulocytosis))

- Severe allergic reactions manifested as various skin eruptions or rashes, breathing problem (for example, the potentially fatal anaphylactic reaction, Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Hypersensitivity reactions called DRESS drug reaction with eosinophilia and systemic symptoms such as Fever, severe rash, joint pain, enlarged lymph nodes and inflammation of one or more internal organs such as liver leading to abdominal pain, yellowing of the skin and whites of the eyes and/or heart, lungs and kidneys; with changes to your blood counts, particularly white blood cells called eosinophils.
- Liver problems (eg. Jaundice –yellowing of skin and white part of eyes)- very rarely can lead to life-threatening liver failure.
- Mental disturbances (psychotic reactions and depression potentially leading to thoughts of suicide and suicide attempts), hallucinations (apparent perception of something not present).
- Inflammation of the bowel (colitis) which causes attacks of diarrhoea, sometimes containing blood and/or mucus) linked to antibiotic use (can be fatal in very rare cases)
- Blood or crystals in the urine, decreased urination (kidney failure)

These are potentially serious side effects and you will need to seek urgent medical attention.

Other side effects are as below

Common: may affect up to 1 in 10 people

- Nausea, diarrhoea
- Joint pains in children

Uncommon: may affect up to 1 in 100 people

- fungal superinfections
- A high concentration of eosinophils, a type of white blood cell
- Decreased appetite
- Hyperactivity or agitation
- Headache, dizziness, sleeping problems, or taste disorders

- Vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), or wind
- Increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- Hives
- Poor kidney function
- Pains in your muscles and bones, feeling unwell (asthenia), or fever
- Increase in blood alkaline phosphatase (a certain substance in the blood)
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania),

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

- Changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- Allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angio-oedema)
- Increased blood sugar (hyperglycaemia)
- Decreased blood sugar (hypoglycaemia)
- Confusion, disorientation, anxiety reactions, strange dreams
- Tremors, seizures or giddiness
- Eyesight problems including double vision
- Tinnitus, loss of hearing, impaired hearing
- Rapid heartbeat (tachycardia)
- Expansion of blood vessels (vasodilation), low blood pressure, or fainting
- Shortness of breath, including asthmatic symptoms
- Liver disorders, jaundice (cholestatic icterus), or hepatitis
- Sensitivity to light
- Urinary tract inflammation
- Fluid retention or excessive sweating
- increased levels of the enzyme amylase

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

- A special type of reduced red blood cell count (haemolytic anaemia); a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal
- Allergic reaction known as serum sickness - migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri) - visual colour distortions
- Inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis- small, pin-point bleeding under the skin (petechiae);

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)
- Pustular rash
- Influence on blood clotting (in patients treated with Vitamin K antagonists)
- Periods of overactive and excited behaviour
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania), hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma).

5. How to store Citizol™?

Store in cool and dry place protect from moisture.

Keep out of reach of children.

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

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™ Trademark

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