

**Patient Information Leaflet (PIL)**  
**BACTALL® 250, 500 and 750 mg**  
**Film Coated Tablet**  
Ciprofloxacin as Ciprofloxacin Hydrochloride

**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 your 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 the leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What **BACTALL** is and what it is used for
2. Before you take **BACTALL**
3. How to take **BACTALL**
4. Possible side effects
5. How to store **BACTALL**
6. Further information.

**1. W T BACTALL IS AND WHAT IT IS USED FOR**

**BACTALL** contains the active substance Ciprofloxacin. Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

**Adults:**

**BACTALL** is used in adults to treat the following bacterial infections:

- Respiratory tract infections
- Long lasting or recurring ear or sinus infections
- Urinary tract infections
- Genital tract infections in men and women
- Gastro-intestinal tract infections and intra-abdominal infections
- Skin and soft tissue infections
- Bone and joint infections
- To prevent infections due to the bacterium *Neisseria meningitidis*
- Anthrax inhalation exposure

Ciprofloxacin may be used in the management of patients with low white blood cell counts (neutropenia) who have a fever that is suspected to be due to a bacterial infection.

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given additional antibiotic treatment in addition to **BACTALL**.

**Children and adolescents:**

**BACTALL** is used in children and adolescents, under specialist medical supervision, to treat the following bacterial infections:

- Lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- Complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis)
- Anthrax inhalation exposure

**2. Before you take BACTALL**

**Do not take BACTALL:**

- If you are allergic to the active substance, to other quinolone drugs or to any of the other ingredients of this medicine (listed in Section 6).
- If you are taking tizanidine (see Section 2: taking other medicines with **BACTALL**).
- To treat infections that might get better without treatment or are not severe (such as throat infections).
- To treat non bacterial infections, e.g. non bacterial (chronic) prostatitis.
- For preventing travelers' diarrhea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder).
- To treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.
- Importantly, **BACTALL** should generally be avoided in patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic. They should be used with special caution in the elderly, patients with kidney disease and those who have had an organ transplantation because these patients are at higher risk of tendon injury. Since the use of a corticosteroid with a fluoroquinolone also increases the risk, combined use of these medicines should be avoided.

**Before taking BACTALL:**

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

**Take special care with BACTALL:**

- Talk to your doctor before taking **BACTALL**:
- If you have ever had kidney problems because your treatment may need to be adjusted.
- If you suffer from epilepsy or other neurological conditions.
- If you have a history of tendon problems during previous treatment with antibiotics such as **BACTALL**.
- 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 you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- If you have been diagnosed with leaking heart valves (heart valve regurgitation).
- If 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 have heart problems. Caution should be taken when using Ciprofloxacin, 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 2: Before you take **BACTALL**).
- If you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anemia with Ciprofloxacin.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to Ciprofloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

**While taking BACTALL:**

Tell your doctor immediately if any of the following occurs while taking **BACTALL**. Your doctor will decide whether treatment with **BACTALL** needs to be stopped:

- 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. If this happens, stop taking **BACTALL** and contact your doctor immediately.
- Prolonged, disabling and potentially irreversible serious side effects. Fluoroquinolone/quinolone antibacterial medicines, including **BACTALL**, 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 **BACTALL**, 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.
- 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 **BACTALL** therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking **BACTALL**, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture.

- 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.

- 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. If seizure happens, stop taking **BACTALL** and contact your doctor immediately.

- 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 **BACTALL** and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- You may experience psychiatric reactions the first time you take **BACTALL**. If you suffer from depression or psychosis, your symptoms may become worse under treatment with **BACTALL**. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.
- Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.

- Diarrhoea may develop while you are taking antibiotics, including **BACTALL**, 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 **BACTALL** and contact your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking **BACTALL**. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking **BACTALL** 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.
- **BACTALL** may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, contact your doctor immediately.

- **BACTALL** 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.

**Taking other medicines with BACTALL:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take **BACTALL** together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: Before you take **BACTALL**).

The following medicines are known to interact with **BACTALL** in your body. Taking **BACTALL** 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 flutidione) or other oral anti-coagulants (to thin the blood)
- Probenecid (for gout)
- Methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- Theophylline (for breathing problems)
- Tizanidine (for muscle spasticity in multiple sclerosis)
- Olanzapine (an antipsychotic)
- Clozapine (an antipsychotic)
- Ropinirole (for Parkinson's disease)
- Phenytoin (for epilepsy)
- Metoclopramide (for nausea and vomiting)
- Cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- 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.
- Zolpidem (for sleep disorders)

**BACTALL 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 anaesthetic use)
- Sildenafil (e.g. for erectile dysfunction)
- Agomelatine (for depression)

**Some medicines reduce the effect of BACTALL.**

**Tell your doctor if you take or wish to take:**

- Antacids
- Omeprazol
- Mineral supplements
- Sucralfat
- 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 **BACTALL** about two hours before or no sooner than four hours after them.

**Taking BACTALL with food and drink:**

Unless you take **BACTALL** during meals, do not eat or drink any dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

**Pregnancy and breast feeding:**

**Pregnancy**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is preferable to avoid the use of **BACTALL** during pregnancy.

**Breast feeding**

Do not take **BACTALL** during breast-feeding because Ciprofloxacin is excreted in breast milk and can be harmful for your child.

**Driving and using machines:**

**BACTALL** may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to **BACTALL** before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

**3. HOW TO TAKE BACTALL**

Your doctor will explain to you exactly how much **BACTALL** 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.

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. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how many tablets to take and how to take **BACTALL**.

- a. Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- b. Do try to take the tablets at around the same time every day.
- c. You can take the tablets at mealtimes or between meals. Any calcium you take as part of meal will not seriously affect uptake. However, do not take **BACTALL** tablets with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Remember to drink plenty of fluids while you are taking this medicine.

**If you take more BACTALL than you should:**

If you take more than the prescribed dose, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

**If you forget to take BACTALL:**

Take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. 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 BACTALL:**

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 about the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECT**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following section contains the most serious side effects that you can recognize yourself: Stop taking **BACTALL** and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

**Rare (may affect up to 1 in 1,000 people)**

- Seizure (see Section 2: Before you take **BACTALL**)

**Very rare (may affect up to 1 in 10,000 people)**

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction/shock) (see Section 2: Before you take **BACTALL**)

- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Before you take **BACTALL**)

- A serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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

- Unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see Section 2: Before you take **BACTALL**)
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEF Acute Generalised Exanthematous Pustulosis). Other side effects which have been observed during treatment with **BACTALL** are listed below by how likely they are:

**Common (may affect up to 1 in 10 people)**

- Nausea, diarrhoea
  - Joint pain and joint inflammation in children
- Uncommon (may affect up to 1 in 100 people)**
- Joint pain in adults
  - Fungal superinfection
  - 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)
  - Rash, itching, or hives
  - Joint pain in adults
  - 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)

**Rare (may affect up to 1 in 1,000 people)**

- Muscle pain, inflammation of the joints, increased muscle tone and cramping
- Inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Before you take **BACTALL**)
- 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) (see Section 2: Before you take **BACTALL**)
- Increased blood sugar (hyperglycaemia)
- Decreased blood sugar (hypoglycaemia) (see Section 2: Before you take **BACTALL**)
- Confusion, disorientation, anxiety reactions, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide (see Section 2: Before you take **BACTALL**), or hallucinations
- Pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures, or giddiness
- Eyesight problems including double vision (see Section 2: Before you take **BACTALL**)
- 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 (see Section 2: Before you take **BACTALL**)

- Kidney failure, blood or crystals in the urine, 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 dangerous drop in a type of white blood cells (agranulocytosis); 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 (see Section 2: Section 2: Before you take **BACTALL**)
  - Allergic reaction called serum sickness-like reaction (see Section 2: Before you take **BACTALL**)
  - Mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (Section 2: Before you take **BACTALL**)
  - 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
  - Death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see Section 2: Before you take **BACTALL**)
  - Small, pin-point bleeding under the skin (petechiae); various skin eruptions or rashes (see Section 2: Take special care with **BACTALL**)
  - worsening of the symptoms of myasthenia gravis (see Section 2: Before you take **BACTALL**)

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

- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- 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)
- Influence on blood clotting (in patients treated with Vitamin K antagonists)
- Loss of consciousness due to severe decrease in blood sugar levels(hypoglycaemic coma).See section 2
- 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.

**5. HOW TO STORE BACTALL**

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Do not use **BACTALL** after the expiry date which is stated on the carton and on the blister, after (EXP).Date

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 BACTALL contains:**

- The active substance is Ciprofloxacin as Ciprofloxacin hydrochloride. Each **BACTALL 250, 500 and 750** tablet contains 250, 500 and 750 mg, respectively, as Ciprofloxacin Hydrochloride.
  - The other ingredients are: microcrystalline cellulose 50 and 180 micrometer, sodium starch glycolate, hydroxypropyl cellulose, colloidal anhydrous silica, magnesium stearate, opadry -OY-21033, white bees wax.
- What BACTALL looks like and contents of the pack:**
- **BACTALL 250** are green circular shallow biconvex film coated tablets debossed with "BA 250" on one side and plain on the other side.
  - **BACTALL 500** are green scored oblong film coated tablets debossed with "BA 500" on one side.
  - **BACTALL 750** are green scored oblong biconvex, film coated tablets.
  - Boxes of 10 blistered tablets of **BACTALL 250**.
  - Boxes of 10 blistered tablets of **BACTALL 500**.
  - Boxes of 10 blistered tablets of **BACTALL 750**.

Health care professionals and patients are encouraged to report adverse events or side effects to JFDA by using:

Email: [jpc@jfda.jo](mailto:jpc@jfda.jo)

Website: [www.jfda.jo](http://www.jfda.jo)

Mobile application: (Jordan fda)

Yellow card form.

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**THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO.**  
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**THIS IS A MEDICAMENT**

□ A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.  
□ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medication.  
□ The doctor and the pharmacist are experts in medicine.  
□ Do not by yourself interrupt the period of treatment prescribed for you.  
□ Do not repeat the same prescription without consulting your doctor.  
□ Keep medications out of the reach of children.

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Prescribing Information Available Upon Request