

JANACIN TABLET

Norfloxacin (400mg)

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What Janacin is used for

For the treatment of acute and chronic urinary tract infections, gastrointestinal infections and gonorrhoea.

How Janacin works

Norfloxacin is a fluoroquinolone antibiotic which kill bacteria by inhibiting DNA synthesis of bacteria.

Before you use Janacin

- When you must not use it

Do not use Janacin if :

- You are allergic (hypersensitive) to norfloxacin or any of the other ingredients of Janacin or quinolone compound.
- You have kidney problem.
- The consumer is a child or young person who is still growing.
- You are pregnant.

Pregnancy and lactation

Do not take Janacin if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Janacin if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

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

- You have moderate kidney disease.
- You have myasthenia gravis (muscle weakness disorder).

Tell your healthcare providers if you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).

Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

Tell your healthcare providers if 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).

You should not take fluoroquinolone antibacterial medicines, including Janacin Tablet, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Especially if you are taking:

- Antacids containing magnesium hydroxide or aluminum hydroxide
- Multivitamins or supplements containing zinc or iron
- Probenecid used to treat gout and hyperuricemia.
- Theophylline used to treat asthma and other lung diseases.

How to use Janacin

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Gonorrhoea – single oral dose of 800mg

Swallow this tablet with a glass of water 1 hour before meal or 2 hours after meal.

Urinary Tract Infections

Orally 200mg – 400 mg twice daily, depending on the condition.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Janacin* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Janacin*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Janacin* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including *Janacin*, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

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 *Janacin* therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking *Janacin*, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

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 *Janacin* and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Janacin may cause phototoxicity (skin reaction which similar to sunburn).

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Janacin* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

The most frequent side effects include nausea, vomiting, abdominal pain, headache, dizziness, crystaluria (cloudy urine) and exacerbation of myasthenia gravis (muscle weakness disorder).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Janacin*

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

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.

Product Description

- What it looks like

Ovoid, biconvex, white film-coated tablet, impressed 'BIOLAB' on one face and bisect on the obverse.

- Ingredients

- Active ingredient
Norfloxacin

- Inactive ingredients
Colloidal silicon dioxide,
Microcrystalline cellulose, Sodium starch glycolate, Magnesium stearate, Hydroxypropyl cellulose, Hydroxypropyl methylcellulose, Isopropyl alcohol, Purified water, Polyethylene glycol, Titanium dioxide, Talcum and Carnauba wax.

- MAL number:

MAL19921583AZ

Manufacturer

BIOLAB COMPANY LTD
625 Soi, 7A, Bangpoo Industrial Estate,
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Product Registration Holder

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