

Patient Information About:

Zagamã (sparfloxacin) 200 mg Tablets

This section contains important information about Zagam (sparfloxacin), and should be read completely before you begin treatment. This section does not take the place of discussions with your health care professional about your medical condition or your treatment. This section does not list all benefits and risks of Zagam. The medicine described here can be prescribed only by a licensed health care professional. If you have any questions about Zagam talk with your health care professional. Only your health care professional can determine if Zagam is right for you.

What is Zagamã ?

Zagam is an antibiotic used to treat lung infections caused by certain germs called bacteria. Zagam kills many of the types of bacteria that can infect the breathing airways and lungs and has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections. Zagam Tablets are white and contain 200 mg of active drug.

Sometimes viruses rather than bacteria may infect the air passages and lungs (for example the common cold). Zagam, like all other antibiotics, does not kill viruses. Your health care professional can help determine whether your symptoms are caused by bacteria and whether Zagam is right for you.

How and When Should I Take Zagam?

Take two tablets of Zagam on the first day, then one tablet once a day for 9 additional days for a total treatment of 10 days. Zagam may be taken with or without food, with a full glass of water, preferably at the same time each day.

In order to make sure that all bacteria are killed and that your symptoms do not recur, you should complete the full course of medication. Do not take more than the prescribed dose of Zagam. If you miss a dose by mistake, do not take a double dose. If it is almost time for your next dose, skip the missed dose and take your regular dose on schedule. Call your health care professional for instructions if you are not sure what to do.

You should contact your health care professional if you think your condition is not improving while taking Zagam.

Who should not take Zagam?

You should not take Zagam if you have ever had a severe allergic reaction to any of the group of antibiotics known as "quinolones" such as ciprofloxacin or levofloxacin.

[THE FOLLOWING TWO PARAGRAPHS WILL BE IN RED]

You should not take Zagam if you have ever had severe sunburn when receiving other medications known to cause sensitivity to sunlight. While taking Zagam and for 5 days after the treatment is stopped, avoid exposure to the sun and sunlamps even when indoors. Phototoxic reactions can occur in patients exposed to shaded or diffuse light, such as through glass or during cloudy days.

You should not take Zagam if your daily activities or occupation entails sun exposure, or if you cannot suspend these activities as required for treatment with Zagam.

You should avoid Zagam if you have a rare condition known as congenital prolongation of the QT interval. If any of your family members have this condition you should inform your health care professional. You should avoid Zagam if you are being treated for heart rhythm disturbances with certain medicines such as disopyramide, quinidine, procainamide, amiodarone or sotalol. Inform your health care professional about all other medications you are taking, especially if you are taking a heart rhythm drug.

You should also avoid Zagam if the amount of potassium in your blood is low. Low potassium can sometimes be caused by medicines called diuretics such as furosemide and hydrochlorothiazide. If you are taking a diuretic medicine you should speak with your health care professional.

If you are pregnant or planning to become pregnant while taking Zagam, talk to your health care professional before taking the medication. Zagam is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

Zagam is not recommended for children.

What are the possible side effects of Zagam?

Zagam is generally well tolerated. The most common side effects caused by Zagam, which are usually mild, include skin sensitivity to sunlight, diarrhea, nausea, headache, indigestion, dizziness, insomnia, abdominal pain, itching, altered taste, vomiting, and flatulence. You should be careful about driving or operating machinery until you are sure Zagam is not causing dizziness. If you notice any side-effects not mentioned in this leaflet or you have concerns about the side effects you are experiencing, please inform your health care professional.

In some people, Zagam, as with some other antibiotics, may produce a small effect on the heart that is seen on an electrocardiogram test. This could result in rare cases of abnormal heartbeat which may be dangerous. Contact your health care professional if you develop heart palpitations (fast beating), or have fainting spells.

Quinolone antibiotics including Zagam have been infrequently associated with ruptures of shoulder, hand, or Achilles tendons. If you develop pain, swelling, or rupture of a tendon you should stop taking Zagam and contact your health care professional.

Convulsions have been infrequently reported in patients receiving quinolone antibiotics including Zagam. If you have experienced convulsions in the past, be sure to let your health care professional know.

Quinolone antibiotics including Zagam have been infrequently associated with allergic reactions, even after just one dose. If you develop hives, skin rash, or other symptoms of an allergic reaction, you should stop taking this medication and call your health care professional.

[The FOLLOWING PARAGRAPH WILL APPEAR IN RED]

If you experience any skin itching, rash, redness, burning or blister formation, or if you experience dizziness or light headedness, IMMEDIATELY STOP taking Zagam and call your health care professional right away.

Which medicines should not be taken with Zagam?

Zagam should not be taken with certain medicines used to treat an abnormal heartbeat. These include quinidine, procainamide, amiodarone, and sotalol.

Some medicines also produce an effect on the electrocardiogram test, including cisapride, erythromycin, some antidepressants and some antipsychotic drugs. These may increase the risk of heart beat problems when taken with Zagam. For this reason it is important to let your health care professional know all of the medicines that you are using.

Some medications including antacids, sucralfate, multivitamins, supplements containing iron, zinc and calcium, may interfere with the absorption of Zagam. If you take these products, you should take them 4 hours after your Zagam dose.

Remember

Take two tablets of Zagam® on the first day then once a day to complete 10 days.

Complete the course of medication even if you are feeling better.

[THE FOLLOWING PARAGRAPH SHOULD APPEAR IN RED]

Avoid exposure to the sun and sunlamps or tanning booths while taking Zagam and 5 days after treatment is stopped. Cover as much of your skin with clothing when brief exposure to the sun cannot be avoided.

Keep this medication out of the reach of children.

This information does not take the place of discussions with your health care professional about your medical condition or your treatment.

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Renata Albrecht
10/2/02 03:58:32 PM