



## Patient Information Sheet

### Clarithromycin (marketed as BIAXIN<sup>®</sup>)

This is a summary of the most important information about clarithromycin. For details, talk to your healthcare professional.

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#### FDA ALERT [12/2005]:

- **In a study done in Denmark using clarithromycin in patients with heart disease, clarithromycin use was associated with a higher chance of death from heart problems.**
- **Clarithromycin is an “antibiotic” or “antibacterial” medicine. Antibiotics have been used before in studies to see if they can help prevent heart disease, and they neither helped nor hurt. This study is the only time that an increase in death in patients with heart disease was seen in patients who had taken clarithromycin.**
- **The FDA and the Danish Medicines Agency (DMA) are not recommending any changes to the use of clarithromycin at this time.**
- **The FDA and the DMA are providing this information to doctors and patients to make them aware of the current information.**

*This information reflects FDA’s preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

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#### What is Clarithromycin?

Clarithromycin is in a class of medicines called macrolide antibiotics. It is used to treat bacterial infections in many parts of the body such as the ears, throat, lungs, sinuses, and skin. It is used in combination with other medicines to treat stomach ulcers caused by bacteria. It is also used for the treatment and prevention of certain types of mycobacterial infections. Clarithromycin does not work for viral infections such as the common cold or flu.

#### Who Should Not Take Clarithromycin?

Do not take clarithromycin if you are allergic to clarithromycin or any of the other macrolide antibiotics such as erythromycin or azithromycin.

#### What are The Risks?

*The following are the major possible risks and side effects of clarithromycin therapy. This list is not complete.*

Some side effects can be serious. The following symptoms are uncommon, but if you get any of them, call your doctor right away:

- severe skin rash
- hives
- itching
- trouble breathing or swallowing
- swelling of the face, throat, eyes, tongue, or lips,
- yellowing of the skin or eyes
- fast, pounding, or irregular heartbeat

*Other side effects:* Some common, but less serious side effects may include diarrhea, nausea, abnormal taste, stomach pain, and headache.

#### What Should I Tell My Healthcare Professional?

Before you start taking clarithromycin, tell your healthcare professional if you:

- Are pregnant or planning to become pregnant
- Are breast-feeding
- Have severe kidney problems

#### Are There Any Interactions With Drugs or Foods?

Clarithromycin and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Do not take clarithromycin with pimozide or astemizole. These medicines can interact, possibly leading to dangerous heart problems.

#### Is There Anything Else I Need To Know?

- Take all of the clarithromycin that has been prescribed for you even if you begin to feel better. Your symptoms may start to improve before the infection is completely treated.

