Biaxin® (clarithromycin) – New warning

- On February 22, 2018, the FDA announced that a new warning will be added to Biaxin (clarithromycin) drug labels regarding a potential increased risk of heart problems or death that can occur years after use.
    - Clarithromycin has been used for more than 25 years, and is sold under the brand name Biaxin and as generics by many different drug companies.
- Like other antibiotics, clarithromycin is used to treat many types of infections affecting the skin, ears, sinuses, lungs, and other parts of the body, including *Mycobacterium avium complex* infection, a type of lung infection that often affects people with human immunodeficiency virus.
    - Clarithromycin is not approved to treat heart disease.
- Healthcare providers should be aware of the significant risks of heart problems and death and weigh the benefits and risks of clarithromycin before prescribing it to any patient, particularly in patients with heart disease and even for short periods, and consider using other available antibiotics.
- Patients with heart disease should be advised of the signs and symptoms of cardiovascular problems, regardless of the medical condition for which clarithromycin is being used for.
- Patients should tell their healthcare provider if they have heart disease, especially when an antibiotic is prescribed to treat an infection. Patients should not stop taking their heart disease medicine or antibiotic without first talking to their healthcare provider. Stopping heart disease or antibiotic therapy could be harmful without a healthcare provider's direct supervision.
- Patients should seek immediate medical attention if they experience symptoms of a heart attack or stroke, such as chest pain, shortness of breath or trouble breathing, pain or weakness in one part or side the body, or slurred speech.
- The safety update is based on CLARICOR, a large clinical trial of 4,373 patients with stable coronary heart disease (CHD) which observed an unexpected increase in all-cause mortality among patients with CHD who received a two-week course of clarithromycin after patients were followed for one year or longer (HR: 1.10, 95% CI: 1.00-1.21).
    - Clarithromycin also increased cerebrovascular disease during the 10 year follow up period (HR: 1.19, 95% CI: 1.02-1.38).
    - There is no clear explanation for how clarithromycin would lead to more deaths than placebo.
- Other observational studies found an increase in deaths or other serious heart-related problems, while others did not.
    - All the studies had limitations in how they were designed. Of the six observational studies published to date in patients with or without coronary artery disease, two found evidence of long-term risks from clarithromycin, and four did not.
    - These study results will be added to clarithromycin drug labels.
- Overall, results from CLARICOR provide the strongest evidence of the increase in risk of heart problems and death compared to the observational study results. Based on these studies, the FDA is unable to determine why the risk of death is greater for patients with heart disease.

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- Furthermore, there are no prospective, randomized, and controlled trials with prespecified long-term safety outcome measures following clarithromycin treatment in patients who do not have heart disease.

- Because the FDA currently does not have study information on patients without heart disease, and observational studies have shown different results, the FDA cannot determine whether results of the CLARICOR trial can be applied to patients who do not have heart disease.

- The FDA is continuing to monitor safety reports in patients taking clarithromycin.

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