Biaxin®/Biaxin® XL (clarithromycin) – New warning

- On June 9, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Biaxin/Biaxin XL (clarithromycin) drug label regarding the risk of all-cause mortality one year or more after the end of treatment in patients with coronary artery disease (CAD).
    - In addition, acute generalized exanthematous pustulosis was added to the acute hypersensitivity reactions warning.
- Clarithromycin is a macrolide antimicrobial indicated for various mild to moderate infections caused by designated, susceptible bacteria.
- In one clinical trial evaluating treatment with clarithromycin on outcomes in patients with CAD, an increase in risk of all-cause mortality one year or more after the end of treatment was observed in patients randomized to receive clarithromycin.
    - Clarithromycin for treatment of CAD is not an approved indication.
    - The cause of the increased risk has not been established.
    - Other epidemiologic studies evaluating this risk have shown variable results.
    - Prescribers should consider balancing this potential risk with the treatment benefits when prescribing Biaxin in patients who have suspected or confirmed CAD.

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