



Food and Drugs Authority

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Distribution list attached

Dear Healthcare Professional,

POTENTIAL FOR INCREASED LONG-TERM RISKS WITH CLARITHROMYCIN IN PATIENTS WITH HEART DISEASE

The Food and Drugs Authority (FDA) wishes to bring to your attention a potential increased risk of heart problems or death that can occur years later in patients with heart diseases who are prescribed with clarithromycin.

This information followed the recent review by the United States Food and Drugs Administration of the results of a 10-year follow-up study¹ of patients with coronary heart disease and from a large clinical trial² that first observed this safety issue.

Meanwhile, the Food and Drugs Authority (FDA) had received two individual case safety reports of cardiovascular related adverse drug reaction described as palpitations to clarithromycin; both patients fully recovered and were also on other medications.

The FDA has informed marketing authorization holders of clarithromycin containing products registered by the Authority to add the new warning about this increased risk of death in patients with heart disease to the product labels.

Prescribers should therefore be aware of these significant risks 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. Prescribers are also to advise patients with heart disease of the signs and symptoms of cardiovascular problems, regardless of the medical condition for they are being treated with clarithromycin.

Clarithromycin is a semi-synthetic macrolide antimicrobial for oral use and registered by the FDA for the following indications when caused by susceptible bacteria; Bacterial pharyngitis, Mild to moderate community acquired pneumonia, Acute bacterial sinusitis (adequately diagnosed), Acute exacerbation of chronic bronchitis, Skin infections and

¹ Winkel P, Hilden J, Fischer Hansen J, et al. Clarithromycin for stable coronary heart disease increases all-cause and cardiovascular mortality and cerebrovascular morbidity over 10 years in the CLARICOR randomised, blinded clinical trial. *International Journal of Cardiology* 2015; 182:459-465.

² Jespersen CM, Als-Nielsen B, Damgaard M, et al. Randomised placebo controlled multicenter trial to assess short term clarithromycin for patients with stable coronary heart disease: CLARICOR trial. *BMJ* 2006;332:22-7.

