

Clarithromycin: Reminder on cardiovascular safety and risk minimisation advice

Clarithromycin is a well-established antibiotic of the macrolide class. It has long been known and reflected in product information that macrolide antibiotics, including clarithromycin, have been associated with effects on QT prolongation and cardiac arrhythmias. Accordingly, the product information for clarithromycin provides guidance on use in patients at risk of ventricular arrhythmia including those with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia, electrolyte disturbances, patients concomitantly taking other medicinal products associated with QT prolongation and patients with congenital or documented acquired QT prolongation or history of ventricular arrhythmia (see sections 4.3 and 4.4 of the Summary of Product Characteristics (SmPC)).

As part of a recent routine periodic assessment of clarithromycin-containing medicines, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) considered the available cumulative evidence to date on the cardiovascular safety of clarithromycin. The PRAC noted that some observational studies have identified a rare short term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including clarithromycin. It is recommended, therefore, that consideration of these findings should be balanced with known treatment benefits when prescribing clarithromycin particularly in patients with a high baseline cardiovascular risk.

The product information for clarithromycin-containing medicinal products will be updated to reflect these findings.

Key Message

- Clarithromycin should be used with caution in patients at increased risk of ventricular arrhythmias.
- In addition, some observational studies have identified a rare short term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including clarithromycin. Consideration of these findings should be balanced with treatment benefits when prescribing clarithromycin in patients with a high baseline cardiovascular risk.
- Any suspected adverse reactions should be reported to the HPRÁ through the available options (www.hpra.ie)

References:

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