HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Amoxicillin – Drug-induced enterocolitis syndrome (DIES)

Amoxicillin* is a semi-synthetic broad spectrum penicillin antibiotic licensed for the treatment of bacterial infections caused by amoxicillin-sensitive gam-positive and gram-negative pathogens.

Following a recent review by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) of the available safety data a causal relationship between amoxicillin and drug-induced enterocolitis syndrome (DIES) is considered at least a reasonable possibility.

DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after drug administration) in the absence of allergic, skin or respiratory symptoms. Further symptoms could comprise of abdominal pain, diarrhoea, hypotension or leucocytosis with neutrophilia. There have been severe cases including progression to shock. DIES has been reported mainly in children receiving amoxicillin.

Product information** will be amended accordingly. These updates apply both to single ingredient amoxicillin medicinal products, and also the amoxicillin-clavulanic acid combination of co-amoxiclav.

**Amoxicillin-containing medicines, including co-amoxiclav products, licensed in Ireland include Amoclav, Amoxicillin/clavulanic acid, Amoxicillin, Augmenting, Clavamel Forte, Germentin, Oramox and Pinamox. Further details are available at www.hpra.ie*

***The approved product information is comprised of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL).*

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