

## **Amoxicillin; Co-Amoxiclav – Very Rare Reports of DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)**

The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has reviewed a signal of drug reaction with eosinophilia and systemic symptoms (DRESS) in association with amoxicillin and co-amoxiclav. It is already known that serious and occasionally fatal hypersensitivity reactions (including anaphylactoid reactions) have been reported in patients on penicillin therapy. Having considered the available evidence in EudraVigilance and in the literature, the PRAC considered that the product information for amoxicillin– and co-amoxiclav–containing medicinal products should be updated to extend warnings about the very rare occurrence of severe cutaneous adverse reactions (SCARs) with amoxicillin to include reference to DRESS (drug reaction with eosinophilia and systemic symptoms).

### **Advice for Healthcare Professionals**

- Amoxicillin has been very rarely associated with serious cutaneous adverse reactions including DRESS (drug reaction with eosinophilia and systemic symptoms).
- Symptoms of DRESS include flu-like symptoms with a rash, fever, lymphadenopathy, and abnormal haematological findings (including eosinophilia and abnormal liver function tests).

### **Key Message**

- Amoxicillin has been associated with very rare reports of drug reaction with eosinophilia and systemic symptoms (DRESS).

*Amoxicillin– and co-amoxiclav–containing medicinal products include Amoclav, Amoxil, Augmentin, Augmentin Duo, Clavamel Forte, Geramox, Germentin, Oramox, and Pinamox. Further details are available on [www.hpra.ie](http://www.hpra.ie).*

*This section has been supplied by the HPRA for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.*