



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 05 February 2019

EL (19)A/03

Our Ref: MDR 92-12/18

Dear Healthcare Professional,

Accord Healthcare Limited

Amoxicillin 500mg Capsules BP

PL 20075/0264

Batch Number	Expiry Date	Pack Size	First Distributed
MP 18062	01/ 2021	1 x 21	04 Oct 2018
MP 18063	01/ 2021	1 x 21	26 Oct 2018
MP 18064	01/2021	1 x 21	16 Oct 2018

Brief description of the problem

Accord Healthcare Limited has informed us that a change to the Patient Information Leaflet (PIL) for this product has not been implemented by the required timeline. The change concerns the addition of the symptoms of a potential side effect, 'Drug Reaction with Eosinophilia and Systemic Symptoms' (DRESS) which is a potentially life-threatening condition. For this reason, it is important that any patients who notice the symptoms seek immediate medical advice.

Advice for healthcare professionals

When dispensing this product, please check the Marketing Authorisation Holder and the batch number. If any of the above batch numbers are being dispensed, please remove the PIL in the pack and provide a copy of the correct version, which can be downloaded from the link below:

<https://www.medicines.org.uk/emc/product/6109/pil>

Further Information

For medical information enquiries, please contact Accord Medical Information, Tel 01271 385257; email medinfo@accord-healthcare.com



Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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