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Important information for healthcare professionals

Amendment to section 4.2 of the Summary of Product Characteristics:

Amoxil® Capsules 250 mg – PL 0038/0103
Amoxil® Capsules 500 mg – PL 00038/0105
Amoxil® Paediatric Suspension 125mg/1.25ml – PL 00038/0107
Amoxil® Sachet 3g Sucrose Free (sachet) – PL 00038/0334

Amoxicillin trihydrate

Date: April 2017

Dear Healthcare Professional

GlaxoSmithKline (GSK) in agreement with the European Medicines Agency and the MHRA would like to inform you of the following:

- The current dosing recommendations for adults undergoing haemodialysis in the EU SmPC have been updated.
- **Section 4.2 of the SmPC has been amended to reflect the correct dosing recommendations for Amoxil in adults and children ≥ 40 kg undergoing haemodialysis.**
- There are no updates to the Patient Information Leaflet as a result of this change.

Revised Labelling

In patients receiving haemodialysis

Amoxicillin may be removed from the circulation by haemodialysis.

	Haemodialysis
Adults and children over 40 kg	500 mg every 24 h Prior to haemodialysis one additional dose of 500 mg should be administered. In order to restore circulating drug levels, another dose of 500 mg should be administered after haemodialysis.
Children under 40 kg	15 mg/kg/day given as a single daily dose (maximum 500 mg). Prior to haemodialysis one additional dose of 15 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15 mg/kg should be administered after haemodialysis.

Action required by Health Care Providers

Healthcare providers are advised to consider the above amendments when prescribing Amoxil in patients undergoing Haemodialysis.

Please share this information with relevant health care personnel under your supervision

Further Information

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ .

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789

- or by downloading and printing a form

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.'

Any serious or unexpected side effects or lack of efficacy/benefit in patients should also be reported by email to uksafety@gsk.com. Alternatively, you can speak to a Safety Advisor by calling 0800 221 441 (option 3).

Contact(s) for Further Information or Questions

For any additional information, please contact our Medical Information Department on 0800 221 441 (option2).

Yours Sincerely,

Dr Hamzah Baig MBBS MRCP MFPM

Associate Country Medical Director UK & Ireland

Person Responsible for Pharmacovigilance UK

UK/RET/0049/17 Apr 2017