Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0300 244 4000
E: medicines.policy@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

19 July 2021

Dear Healthcare Professional,

DRUG ALERT CLASS 4 - 18 2021 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – Brown & Burk UK Limited - Amoxicillin 500 mg/ 5 ml Powder for oral suspension

Please see the attached drug alert for onward transmission as below.

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely,

Elliot Paton
Medicines Policy

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 19 July 2021 EL (21)A/18 Our Ref: MDR 232-06/21

Dear Healthcare Professional,

Brown & Burk UK Limited

Amoxicillin 500 mg/ 5 ml Powder for oral suspension PL 25298/0248

Batch Number	Expiry Date	Pack Size	First Distributed
ASDBV0001	Nov.2022	100ml (When reconstituted)	14 June 2021
ASDBV0002	Nov.2022	100ml (When reconstituted)	Not yet distributed
ASDBV0003	Nov.2022	100ml (When reconstituted)	Not yet distributed

Active Pharmaceutical Ingredient: Amoxicillin trihydrate

Brief description of the problem
Brown & Burk UK Limited would like to notify you of an error regarding specific batches of Amoxicillin 500 mg/ 5 ml Powder for oral suspension, sold and distributed in the UK. The product information incorrectly states the quantity of the excipient sodium benzoate. The actual quantity of sodium benzoate is 3.75mg/5ml. On the PIL it is incorrectly reported as 7.5mg/5ml and in the SmPC it is 15mg/5ml (1.5mg/ml)

Advice for healthcare professionals
There is no risk to product quality as a result of this issue, therefore the associated batches are not being recalled at this time. The batches not yet distributed have been included in this alert to inform HCPs accordingly. These batches were subject to a batch specific variation, assessed by the MHRA and it was considered that the risk associated with the incorrect information was low and therefore no market action considered.

The product information is in the process of being revised to reflect the correct quantity of sodium benzoate and new batches will be only be distributed with the correct information

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

Further Information
For more information, medical information queries please contact: pv@bbukltd.com

For stock enquiries please contact: customercare@bbukltd.com or 0203 384 7188

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574