



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy and Ward Level

Date: 19 December 2017

EL (17) A/14

Our Ref: MDR 33-12/17

Dear Healthcare Professional,

Wockhardt UK Ltd

| | |
|--|----------------------|
| Co-Amoxiclav 1000mg/200mg Powder for Solution for Injection or Infusion | PL 29831/0043 |
| Amoxicillin / Clavulanic Acid | |

| Batch Number | Expiry date | Pack Size | First Distributed |
|---------------------|--------------------|------------------|--------------------------|
| M040 | 31 May 2019 | 1 x 10 | 04 Oct 2017 |
| M041 | 31 May 2019 | 1 x 10 | 11 Oct 2017 |
| M042 | 31 May 2019 | 1 x 10 | 14 Oct 2017 |
| M043 | 31 May 2019 | 1 x 10 | 26 Oct 2017 |
| M044 | 31 May 2019 | 1 x 10 | 03 Nov 2017 |
| M045 | 30 Jun 2019 | 1 x 10 | 08 Nov 2017 |
| M046 | 30 Jun 2019 | 1 x 10 | 14 Nov 2017 |

Background

Wockhardt UK Ltd has informed us that they have received an atypical number of complaints of discolouration concerning the above batches for both reconstituted and unreconstituted vials. An investigation has identified that all the above batches were filled on an alternative filling line by their contract manufacture and an issue during filling has resulted in up to 5% of vials from these batches being discoloured. All previous and subsequent batches were filled on the usual line and are unaffected by this issue.

Action

In order to avoid product shortages, the above batches are not being recalled. Wockhardt has recommended the following action:

- Inspect the contents of individual vials prior to reconstitution. The powder is normally white to almost white. Any vials in which the powder is cream coloured should be discarded.
- Inspect the solution in the vials after reconstitution. This should be colourless to a pale straw colour. Any vials containing solution which is a darker colour should be discarded.

Affected vials appear randomly in individual packs.



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Contact details

If any discoloured vials are identified, please notify the Quality Complaints group on 01978 661261 or email Quality.Complaints@wockhardt.co.uk

For medical Information enquiries, please contact Medical Information on 01978 661261 or email drug.safety@wockhardt.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce

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