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Direct Healthcare Professional Communication

Caution in Use: Amoxicillin Sodium 250mg Powder for Solution for Injection
CPSU Product licence AA565/26703 (Wockhardt**;** PL29831/0010)

Following a Class 4 Drug Alert in the UK regarding Wockhardt UK's Amoxicillin, the Central procurement and Supplies Unit in agreement with the Malta Medicines Authority would like to inform you of the following:

Summary

- **Amoxicillin Sodium 250mg Powder for Solution for Injection (all strengths and all batches) is associated with reports of extravasation and injections site reactions in neonates and infants (below 1 year old)**
- **Although no root cause has been confirmed for these events, an investigation identified contributing factors, which are currently considered to be resolved**
- **Based on MHRA's review of available data, the Commission on Human Medicines' Paediatric Medicine Expert Advisory Group (PMEAG) has advised that Wockhardt UK's Amoxicillin Sodium Powder for Solution for Injection can be used with caution in neonates and infants**
- **Healthcare professionals are asked to exercise caution when using these products and monitor the cannula site before, during and after administration; administration should be stopped immediately if extravasation or injection site reactions are suspected**
- **Healthcare professionals should report extravasation events and any suspected adverse drug reactions with these products directly to the Malta Medicines Authority via the adverse drug reaction form.**

Background

In July 2014, a Class 4 Drug Alert was issued in the UK asking healthcare professionals not to use Wockhardt UK Amoxicillin Powder for Solution for Injection (all strengths and all batches) in neonates and infants (below 1 year old), following receipt of a number of reports of extravasation and injections site reactions.

This was followed by a Class 2 Drug Alert, recalling three batches of Wockhardt UK's Amoxicillin Sodium 500mg Powder for Solution for Injection, which were investigated. Although the recalled batches had parameters out-of-trend with usual batches, they were not identified as defective.

Wockhardt UK has revised the finished product and Active Pharmaceutical Ingredient specifications to include a tightened pH specification and introduced limits for osmolality for the reconstituted product.

In May 2020, following a MHRA review of all data available since the alert, the Committee on Human Medicines' PMEAG advised that Wockhardt UK's Amoxicillin Sodium Powder for Solution for Injection could be used in neonates and infants (below 1 year old).

Advice for Healthcare Professionals:
Caution and monitoring should be exercised during the use of these products for the development of extravasation or injection site reactions.

In order to minimise the risk of extravasation or injection site reactions a number of precautions should be taken:

- Wockhardt UK's Amoxicillin Sodium Powder for Solution for Injection should be prepared and administered in accordance with section 4.2, Method of administration, of the Summary of Product Characteristics.

- For more information, see https://www.medicines.org.uk/emc/product/1358/smpc

- The cannula site should be observed and monitored before, during and after administration of Amoxicillin Sodium Powder for Solution for Injection.

- Patency of the cannula should be maintained.

- If extravasation or injection site reactions are suspected, the administration of Amoxicillin Sodium Powder for Solution for Injection should be stopped immediately and the appropriate procedures in line with local guidelines should be followed.

Call for reporting
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.