24 August 2020 Direct Healthcare Professional Communication

Wockhardt UK's Amoxicillin Sodium 250mg, 500mg and 1g Powder for Solution for Injection: caution and monitoring requirements

Wockhardt UK, in agreement with MHRA, would like to inform you of the following:

Summary

- In 2014, a Class 4 Drug Alert asked healthcare professionals not to use Wockhardt UK's Amoxicillin Sodium Powder for Solution for Injection (all strengths and all batches) in neonates and infants (below 1 year old) following reports of extravasation and injections site reactions; batches of the 500mg product were subsequently recalled
- 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 and local guidelines followed
- Healthcare professionals should report extravasation events and any suspected adverse drug reactions with these products to the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) – please include the suspected brand and batch number of amoxicillin sodium powder

Background

On 9 July 2014, a Class 4 Drug Alert (EL (14)A/09) was issued 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. A Class 2 Drug Alert (EL (14)A/11) followed on 22 July 2014, recalling three batches of Wockhardt UK's Amoxicillin Sodium 500mg Powder for Solution for Injection.

The recalled batches were investigated and although they 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 including all cases of adverse events reported 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). Caution and monitoring should be exercised during the use of these products for the development of extravasation or injection site reactions.

Advice for healthcare professionals

To minimise the risk of extravasation or injection site reactions a number of precautions should be taken, and relevant local policies and procedures should be followed:

- 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 with a medicinal product is important. Healthcare professionals are asked to report any suspected adverse reactions following the administration of Wockhardt UK's Amoxicillin Sodium Powder for Solution for Injection.

Particular emphasis should be placed on reporting injection site/extravasation related adverse reactions in all patients. These reports should also state the suspected brand and batch number of Amoxicillin Sodium Powder for Solution for Injection, if this is available.

Healthcare professionals should report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free

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

Company contact point

If you have any questions about this letter or for more information about Amoxicillin Sodium Powder for Solution for Injection, please contact Wockhardt Drug Safety & Information at Wockhardt UK Ltd, Ash Road North, Wrexham Industrial Estate, Wrexham, LL13 9UF or Telephone: 01978 661261

Sincerely,

Gabor Varbiro, MD, PhD, MBA

Medical Director

Wockhardt UK Ltd