19th June 2014

Risks identified with reformulated Dexamethasone 6.6 mg/2 ml Solution for Injection

AA 734/01401

Dear Healthcare Professional,

In agreement with the Medicines Authority, Hospira UK Limited would like to inform you of the following:

Summary

- **Hospira recently changed the formulation of Dexamethasone 6.6 mg/2 ml Solution for Injection to include sodium sulphite as an antioxidant to enhance product stability.**
- **This sulphite-containing formulation has an altered risk profile compared to the previous sulphite-free formulation. The following potential risks have been identified with the reformulated product:**
  - **The excipient sodium sulphite may rarely cause severe hypersensitivity reactions and bronchospasm.**
  - **There is a potential risk of neurotoxicity if administered intrathecally.**
- **The reformulated product is contraindicated in patients with a known hypersensitivity to sulphites.**
- **This formulation should not be administered intrathecally due to the potential for harm. This is reflected in warning statements on the revised vial label and carton which state "For Intravenous, Intramuscular, Intraarticular or Intralesional Use Only. Harmful if given by other routes - Contains Sulphites",**
- **This change affects the Dexamethasone 6.6 mg/2 ml Solution for Injection vial presentation only; Hospira continue to offer a sulphite-free formulation in the Dexamethasone 3.3 mg/mL Solution for Injection ampoule.**

Background

A literature review identified equivocal data regarding the effects of sulphites administered intrathecally, however cases of arachnoiditis, chemical meningitis and local neural toxicity have been reported and attributed to sulphites administered intrathecally. This as well as neurotoxicity from animal models suggests intrathecal injection of sulphite-containing dexamethasone may potentially result in neurotoxicity.

In addition, the literature review identified the potential risk of hypersensitivity reactions and bronchospasm to sulphites; consequently the reformulated product is contraindicated in patients that have known hypersensitivity to sulphites.

As a consequence the product information is being updated as agreed with the Medicines Authority.

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The new formulation has the same indications and directions for use as the previous formulation. Dexamethasone 6.6 mg/2 ml Solution for Injection is approved for administration by intramuscular, intra-articular or direct intravenous injection, intravenous infusion or soft tissue infiltration.

The new formulation is provided within an **amber** vial. The original, sulphite-free formulation is provided within a clear vial. Please consult the Package Leaflet or Summary of Product Characteristics for more information.

Please inform all relevant healthcare professionals in your organisation of this notification.

Call for reporting

Healthcare professionals should report any adverse reactions to
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

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

Additionally, any such information may be reported to Drugsales Ltd on Tel: +356 21 419 070/1/2 or email safety@drugsalesltd.com

Company contact point

Should you have any questions or require additional information regarding the use of Hospira products, please contact Medical Information on Tel: + 44 (0) 1926 820820

Yours sincerely,

[signature to be added]

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Responsible Person/Regulatory Affairs officer
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