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Worldwide Biopharmaceutical Businesses

Direct Healthcare Communication

7th January 2021

Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection

Potential risk of medication errors following reformulation from a lactose-containing to a lactose-free formulation

Dear Healthcare Professional,

Pfizer Healthcare Ireland in agreement with the Health Products Regulatory Agency (HPRA) would like to inform you of the following:

Summary

- Pfizer Healthcare Ireland has reformulated Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection to a lactose-free formulation where the lactose is replaced by sucrose and plans to initiate transition to the lactose free formulation on 30th January 2021. Pfizer will stop distributing the lactose-containing product starting from 28th February 2021.
- The following precautionary measures will be implemented in order to help clearly distinguish and differentiate between the old (lactose-containing) and new (lactose-free) formulations and to help avoid potential medication errors:
- a clarifying statement ("lactose free") on both the outer carton and vial labels to denote that these are lactose free formulations,
- a change of Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection cap colour from "orange" back to "white" for the new formulation (lactose-free),
- a change of colour of both the outer carton artwork and the vial label artwork,
- updated Product Information.

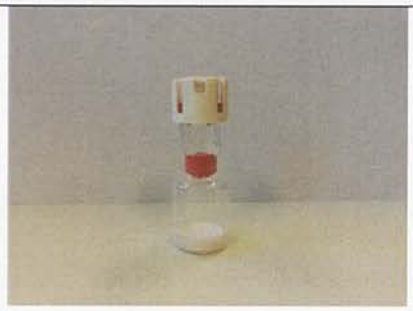
Registered in England: No 526209
Registered Office: Ramsgate Road
Sandwich, Kent CT13 9NJ, UK

Detailed description of the precautionary measures to be implemented:

1) The new formulation of Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection will feature a revised outer carton and vial label which includes a clarifying statement with the following wording (see reproduction below):

LACTOS FREE	This labelling provides a clear distinction between the two current formulations (lactose containing and lactose free)

2) The new formulation of Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection will have a white cap to differentiate between the current and new formulations.

Current formulation (lactose containing)	**New formulation (lactose free)**
	

3) The new formulation of Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection will be packaged in a carton with revised labelling. Vial labels will also be revised. Please see below for a comparison of the current (lactose-containing) and new (lactose free) carton and vial labels.

Revised Outer Carton and Vial Labelling for Solu-Medrone (methylprednisolone sodium succinate) 40 mg powder and solvent for solution for injection:

Current formulation (lactose containing)

Outer carton

Vial Label

New formulation (lactose free)

Outer Carton

Vial Label

It is important that patients who are allergic to lactose and require the new (lactose-free) formulation **DO NOT** inadvertently receive a lactose-containing formulation.

Instructions

Prescribers are instructed to ensure patients who are allergic to lactose and who require the new lactose- free formulation are prescribed 'Solu -Medrone injection 40mg **lactose free**' or 'methylprednisolone injection 40mg **lactose free**.'

Background on the safety concern

The reformulation was a requirement by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) following reports of serious allergic reactions in patients allergic to cow's milk proteins who were treated intravenously or intramuscularly with 40 mg and 20mg presentations of methylprednisolone products containing bovine lactose. The product labelling in the EU for formulations of Solu-Medrone methylprednisolone sodium succinate containing bovine lactose had

been revised as an interim measure to provide clear guidance on use in patients who may be allergic to cow's milk proteins until reformulated product was available. The revisions for interim labelling included:

- A contraindication specifying that methylprednisolone injections containing lactose must not be given to patients known or suspected to be allergic to cow's milk proteins, as it may contain traces of milk ingredients.
- A warning specifying that allergic reactions to cow's milk proteins should be considered in patients receiving Solu-Medrone methylprednisolone sodium succinate 40mg/ml for the treatment of acute allergic conditions in whom symptoms worsen or who are presenting new allergic symptoms. In these patients, administration of Solu-Medrone methylprednisolone sodium succinate 40mg should be stopped, and the patient's condition should be treated accordingly.
- These changes are no longer applicable and have been removed from the product information.

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse events to the Health Products Regulatory Authority, via HPRA Pharmacovigilance, website: www.hpra.ie.

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 1800 633 363.

Company contact point

For more information about Solu-Medrone, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Tel: 1800 633 363 and ask for Medical Information.

Yours sincerely

E McGettrick.

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