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Saudi Arabia

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Letter to healthcare professionals regarding the contraindication for use of Solu-Medrol 40 mg powder and solvent for solution for injection in patients with a known or suspected hypersensitivity to cow's milk or its components, or other dairy products

Dear Healthcare Provider,

Pfizer Saudi Limited would like to inform you of the following:

Summary

- Solu-Medrol® 40 mg powder and solvent for solution for injection presentations include lactose monohydrate produced from cow's milk. Serious allergic reactions, including bronchospasm and anaphylaxis have been reported in patients allergic to cow's milk proteins who were treated intravenously or intramuscularly with 40 mg presentations of methylprednisolone products containing lactose. These presentations are therefore contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its components, or other dairy products, because they may contain trace amounts of milk ingredients.

- If a patient has signs or symptoms of hypersensitivity following administration of Solu-Medrol®, administration should be stopped, and the patient should be treated accordingly.

- In the treatment of acute allergic conditions, the use of corticosteroids which do not contain lactose from animal sources should be considered where appropriate, as use of Solu-Medrol® in individuals with hypersensitivity to milk proteins has the potential to exacerbate the condition.

Further information on the safety concerns and recommendations:

In a very small number of cases, patients who were hypersensitive to milk developed severe hypersensitivity reactions following the use of methylprednisolone sodium succinate which contained lactose. Hypersensitivity to milk is distinct from intolerance to lactose-containing foods. Lactose intolerance is a non-immunologically mediated reaction to milk caused by a lack of the enzyme lactase in the small intestine, which converts lactose into glucose and galactose. Methylprednisolone sodium succinate Solu-Medrol® 40-mg powder and solvent for solution for injection contain lactose as an excipient, which is derived from cow's milk and, therefore, can contain cow's milk proteins in trace amounts.

If after the administration of methylprednisolone sodium succinate Solu-Medrol® 40 mg containing lactose a patient has signs or symptoms of hypersensitivity, or if these symptoms worsen, administration of Solu-Medrol® should be stopped, and the patient should be treated accordingly.

In the treatment of acute allergic conditions, the use of corticosteroids which do not contain lactose from animal sources should be considered if appropriate as use of Solu-Medrol® in individuals with hypersensitivity to milk proteins may exacerbate the condition.

Pfizer Methylprednisolone sodium succinate Solu-Medrol®125 mg, 250 mg, 500 mg, 1000 mg and 2000 mg powder and solvent for solution for injection do not contain lactose. Pfizer methylprednisolone acetate Depo-Medrol® and Pfizer hydrocortisone sodium succinate Solu-Cortef® also do not contain lactose.

Pfizer is unable to provide information regarding the composition (or sources of lactose, if the product contains lactose) in formulations of methylprednisolone sodium succinate not manufactured by Pfizer.

This information is being sent in agreement with the Saudi Food & Drug Authority.

Call for reporting
Reporting of adverse reactions

All suspected adverse reactions should be reported to via:

National Pharmacovigilance and Drug Safety Center (NPC):
By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/

Pharmacovigilance department in the company:

- Email: SAU.AEReporting@Pfizer.com
- Fax: 012 22 93692

Yours sincerely,

Dr. Mohamed Fathy
Country Medical Director
Pfizer Saudi Arabia