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Direct Healthcare Professional Communication

**Solu-Medrone 40 mg Injection**

**Injectable methylprednisolone products containing lactose: new contraindication in patients allergic to cow's milk proteins treated for allergic conditions**

Dear Healthcare Professional,

The Central Procurement and Supplies Unit (CPSU) within the Ministry for Health, in agreement with the Malta Medicines Authority would like to inform you of the following safety concern


**Summary**

- Injectable methylprednisolone products containing lactose of bovine origin can cause serious allergic reactions in patients allergic to cow's milk proteins when given for allergic reaction.
- **The risk of allergic reactions in patients allergic to cow's milk proteins and treated for allergic conditions is limited to the lactose-containing strengths of Solu-Medrone 40 mg [UK MHRA no: PL 00057/1045]. Pfizer UK indicated that other strengths of Solu-Medrone do not contain lactose.**
- **This product is now contraindicated in patients with a known or suspected allergy to cow's milk.**
- Lactose produced from cow's milk is used as an excipient in this product and may contain trace amounts of milk proteins, which can trigger an allergic reaction in patients allergic to cow's milk proteins.
- In patients receiving this product for the treatment of acute allergic conditions in whom symptoms worsen or any new allergic symptoms occur, allergic reaction to cow's milk proteins should be suspected.
- Administration of the product should be stopped in these patients, and the patient's condition should be treated accordingly.


**Background of the safety concern**

Cases of allergic reactions, most serious, including bronchospasm and anaphylaxis, have been reported in patients allergic to cow's milk proteins who were treated for acute allergic conditions with injectable methylprednisolone products containing lactose of bovine origin. The majority of patients were younger than 12 years. In some of the reported cases the adverse reaction was misinterpreted as a lack of therapeutic effect, leading to re-administration of methylprednisolone and subsequent worsening of the patient's clinical condition. The patients recovered in all cases for which the outcome was reported.

Cow's milk allergy (CMA) is an adverse reaction of an immunological nature induced by cow's milk proteins. Estimates of prevalence of CMA based on food challenge vary from 0% to 3%. Most children outgrow their CMA in early childhood and only a smaller proportion of patients remain allergic in adulthood. CMA should be clearly distinguished from lactose intolerance, which is a non-immunologically mediated reaction to milk caused by a lack of the enzyme lactase in the small intestines, which breaks lactose from milk down into glucose and galactose.

Following an EU-wide review of this issue, methylprednisolone products containing lactose produced from cow's milk for IV/IM use in acute allergic conditions will be reformulated to remove any trace of milk proteins. In the interim, the product information will be updated with the contraindication and warnings related to the risk of allergic reactions in patients allergic to cow's milk proteins. Solu-Medrone 40 mg Injection uses lactose produced from cows' milk as an excipient and may contain trace amounts of milk protein. No other medicines containing bovine lactose are authorised for use in acute allergic conditions in the EU.

## Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system. Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt

## CPSU contact point

If you have further questions or require additional information please contact:

Central Procurement and Supplies Unit (within the Ministry for Health), San Ġwann Industrial Estate, Malta on

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Yours faithfully,

**Post-Licensing Directorate**
**Medicines Authority**

Disclaimer
*This Direct Healthcare Professional Communication has been submitted to you on behalf of the Central Procurement & Supplies Unit*