



Worldwide Biopharmaceutical Businesses

October 2017

Solu-Medrone 40 mg

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

Dear Healthcare professional,

Pfizer Ltd., in agreement with the European Medicines Agency and the MHRA, would like to inform you of the following:

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 reactions.
- 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.
- 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 these products only:

Solu-Medrone 40 mg
PL 00057/1045
PIP Code 026-6627

Background on the safety concern

Cases of allergic reactions, most serious, including bronchospasm and anaphylaxis, were 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.

The present recommendations are made following an EU-wide review of this issue which covered all methylprednisolone products containing lactose produced from cow's milk for IV/IM use in acute allergic conditions. The products will be reformulated to remove any trace of milk proteins. In the interim, the product information will be updated with the above contraindication and warnings related to the risk of allergic reactions in patients allergic to cow's milk proteins. No other medicines containing bovine lactose are authorised for use in acute allergic conditions in the EU.

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.

Call for reporting

Any suspected adverse events should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard.

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the Yellow Card section of the MHRA website

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 01304 616161.

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

Telephone: 01304 616 161, or

Medical information website www.pfizermedicalinformation.co.uk

Yours faithfully,

Seema S Patel
Pfizer Essential Health Medical Director, UK