7 July 2017
EMA/416655/2017

PRAC recommends that injectable methylprednisolone products containing lactose must not be given to patients allergic to cow's milk proteins

Companies to replace all current formulations containing lactose with lactose-free formulations

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that injectable methylprednisolone medicines containing lactose, which potentially contain traces of cow's milk proteins, must not be used in patients with a known or suspected allergy to the proteins in cow's milk.

In addition, patients being treated for an allergic reaction with methylprednisolone should have their treatment stopped if their symptoms worsen or they develop new symptoms.

These recommendations follow a review which found that lactose derived from cow's milk may introduce traces of cow's milk proteins into the medicine which can trigger reactions in patients allergic to these proteins. This is of particular concern in patients already being treated for an allergic reaction as they are more prone to developing new allergic reactions. In this case it may be difficult to determine whether the patient's symptoms are due to a new allergic reaction caused by methylprednisolone products containing lactose or due to a worsening of the original condition. This may lead to additional doses being given which will further worsen the patient's condition.

Allergy to cow's milk proteins affects a small percentage of the population (up to 3 people in 100) and should not be confused with lactose intolerance which is a separate condition.

The PRAC concluded that there is no level of cow milk proteins that can be considered safe for these medicines when used to treat severe allergic reactions. Considering that methylprednisolone is used for the treatment of severe allergic reactions in an emergency setting where details of the patients' known allergies may not always be known, the PRAC recommended that the most effective way of minimising any risks is to remove cow's milk proteins from the preparation. The Committee therefore asked companies to take steps by middle of 2019 to replace current formulations containing cow's milk proteins with formulations that do not contain these proteins.

In the meantime, the product information will be revised to reflect that injectable methylprednisolone products containing lactose must not be given to patients allergic to cow's milk proteins

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

and healthcare professionals will be informed in writing of this risk. In addition, the vial and packaging of these medicines will be clearly marked with a warning against use in patients with cow's milk allergy.

The PRAC recommendation will be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. Further details including advice for patients and healthcare professionals will be published at the time of the CMDh position.

More about the medicine

The review covered certain injectable medicines which contain the corticosteroid methylprednisolone and are used to treat the symptoms of severe allergic reactions and other inflammatory conditions. Specifically, the review covered the strengths of injections that contain lactose (milk sugar) derived from cows' milk and hence can contain traces of cows' milk proteins. Methylprednisolone-containing medicines have been authorised by national procedures for use by injection into a vein or muscle and have been available for many years in the EU under a variety of brand names including Solu-Medrol.

Corticosteroids are anti-inflammatory medicines used to control the immune system (the body's natural defences) when it is overactive, as in allergic conditions.

More about the procedure

The review of injectable medicines for acute allergic reaction that contain lactose from cows' milk was initiated on 1 December 2016 at the request of Croatia, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. The PRAC recommendations will now be sent to Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.