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EMA to review certain injectable medicines to treat allergy

Risks of some methylprednisolone products in patients allergic to cows' milk proteins to be investigated

The European Medicines Agency (EMA) has started a review of certain medicines given by injection to treat severe, rapidly developing (acute) allergic reactions. The medicines involved contain the corticosteroid methylprednisolone as active ingredient. They also include as an additional ingredient lactose (milk sugar), which potentially contains traces of cows' milk proteins that could affect treatment of acute reactions in the small number of highly sensitive patients allergic to these proteins.

The review is triggered by reports of patients treated for allergic conditions with these medicines, who were also allergic to cows' milk proteins. The medicine itself apparently caused an allergic reaction in these patients. In such circumstances, the reaction to the medicine may be mistaken for a worsening of the original condition, leading to additional doses of the medicine being given.

EMA will evaluate the available data on the risk of an allergic reaction to the medicine itself, and consider whether there is a need for measures to minimise the risk. The scope of the review has been limited to these allergy medicines where patients may be more sensitive and confusion between the condition and the reaction to the medicine can lead to incorrect treatment. However, it is expected that any findings from the review will contribute to work that is already ongoing to improve information for patients and doctors about all medicines that contain lactose as an additional ingredient.

Allergy to cows' milk protein affects a small percentage of the population (around 2 to 50 people in 1000) and should not be confused with lactose intolerance which is a separate condition.

More about the medicines

The review covers certain injectable medicines which contain the corticosteroid methylprednisolone and are used to treat the symptoms of severe allergic reactions. Specifically, the review covers those strengths of the medicines that contain lactose (milk sugar) derived from cows' milk and hence can contain traces of cows' milk proteins. These 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. Other similar medicines that do not contain lactose from cows' milk are also widely available.

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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 is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then 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.

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