13 February 2015
EMA/85678/2015

PRAC recommends new measures to minimise known heart risks of hydroxyzine-containing medicines

Medicines can still be given for their approved uses, with new restrictions

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of medicines containing the antihistamine hydroxyzine. This follows concerns over the risk of possible effects on heart rhythm with these medicines, which are available in most EU countries. Their approved uses (indications) vary considerably between countries and may include use to treat anxiety disorders, for relief of pruritus (itching), as premedication before surgery, and for treatment of sleep disorders.

The PRAC considered that hydroxyzine was associated with a small but definite risk of QT interval prolongation and torsade de pointes (alterations in the electrical activity of the heart that can lead to abnormal heart rhythms and cardiac arrest). Based on the assessed data, the risk did not differ between indications, and the Committee recommended that hydroxyzine could continue to be used provided that measures to minimise the risk of problems with heart rhythm were taken.

These measures include using the medicine at the lowest effective dose for as short a time as possible. Use is not recommended in the elderly. The maximum daily dose should be no more than 100 mg in adults (50 mg in the elderly if use cannot be avoided), and 2 mg per kg body weight where used in children up to 40 kg in weight. Use must be avoided in patients who already have risk factors for heart rhythm disturbances or are taking other medicines that increase the risk of QT prolongation. Care is also needed in patients taking medicines that slow the heart rate or decrease the level of potassium in the blood, as these also increase the risk of problems with heart rhythm.

The PRAC recommendation follows a detailed review of the available evidence, which included published studies and data from regular safety monitoring, as well as consultation with experts in the treatment of children and the elderly. PRAC confirmed the known possibility of QT interval prolongation and torsade de pointes with hydroxyzine, and noted that such events were most likely to occur in patients who had risk factors. The risk can therefore be decreased by restricting hydroxyzine use in those most at risk of heart rhythm problems and reducing exposure to the medicine. The Committee recommended further study and monitoring to ensure that these measures were effective. The product information should be updated accordingly.

The PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position and provide guidance to patients and healthcare professionals. In the interim, patients who have any concerns should consult their doctor or pharmacist.

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More about the medicine

Hydroxyzine-containing medicines have been authorised by national procedures in 22 Member States of the EU (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and United Kingdom) plus Norway and Iceland. They are used generally by mouth or sometimes by injection under various trade names including Atarax. Approved uses vary between countries, but may include treatment of anxiety disorders, relief of pruritus (itching) including that due to urticaria, premedication before surgery, and treatment of sleep disorders.

More about the procedure

The review of hydroxyzine was initiated on 25 April 2014 at the request of Hungary, 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 now made a set of recommendations. As hydroxyzine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to CMDh, which will adopt a final position. The CMDh, a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

If the CMDh position is agreed by consensus, the agreement will be directly implemented by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission, for the adoption of an EU-wide legally binding decision.

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