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Review of hydroxyzine-containing medicines started

The European Medicines Agency has started a review of hydroxyzine-containing medicines, which have been approved in most EU countries for a variety of uses including anxiety disorders, as premedication before surgery, for relief of pruritus (itching), and for sleep disorders.

The review was requested by the Hungarian medicines agency (GYEMSZI-OGYI) over concerns about the side effects of these medicines on the heart. This followed an examination of the benefits and risks by a marketing authorisation holder for hydroxyzine. Data from drug safety monitoring (pharmacovigilance) and published experimental studies identified a potentially increased risk of alterations of the electrical activity of the heart and arrhythmias (irregular heartbeats). As hydroxyzine-containing medicines are approved in other EU countries, the Hungarian agency decided to trigger an EU-wide review.

The European Medicines Agency will now review the available data on the benefits and risks of hydroxyzine-containing medicines in all authorised indications, and issue an opinion on the marketing authorisations of these medicines across the EU.

While the review is ongoing, patients should speak to their doctor or pharmacist if they have any questions or concerns.

More about the medicine

Hydroxyzine is a medicine that has 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. It is used generally by mouth or sometimes by injection under various trade names including Atarax. Its approved uses vary between countries, but may include relief of anxiety disorders, premedication before surgical procedures, relief of urticaria or various other conditions associated with pruritus (itching), and treatment of sleep disorders.

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More about the procedure

The review of hydroxyzine has been initiated at the request of Hungary, 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. As hydroxyzine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (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.