New restrictions to minimise the risks of effects on heart rhythm with hydroxyzine-containing medicines (Atarax®)

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The European Medicines Agency's Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has agreed by consensus new measures to minimise the risk of effects on heart rhythm with medicines containing the antihistamine hydroxyzine. The CMDh, a medicines regulatory body with members representing each of the EU Member States has agreed that the use of hydroxyzine should be restricted in patients at high risk of heart rhythm problems and that the medicine should be used at the lowest effective dose for as short a time as possible.

Recommendations for these new measures were originally made by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and are given in the sections below addressed to Healthcare professionals. Having assessed the available evidence, including published studies and data from regular safety monitoring, the PRAC concluded that the risk did not differ between indications and that such events are most likely to occur in patients who have risk factors. The PRAC therefore recommended that the risk be managed by restricting hydroxyzine use in those most at risk of heart rhythm problems and reducing exposure to the medicine.

As the CMDh has now agreed the PRAC measures by consensus, the measures will be directly implemented by the Member States where the medicines are authorised, according to an agreed timetable. In particular, the product information of hydroxyzine-containing medicines will be updated with new dosing recommendations and warnings on use in patients who have risk factors for heart rhythm disturbances or who are taking certain other medicines. In Malta, the product information (Summary of Product Characteristics and Patient Information Leaflet) of the following medicinal products will be updated with this information.

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Hydroxyzine Dihydrochloride 2mg/ml	Atarax syrup	SYRUP	PoM	MA030/00101	UCB Pharma SA
Hydroxyzine Dihydrochloride 25mg	Atarax	FILM-COATED TABLET	PoM	MA030/00102	UCB Pharma SA

In Malta

For Healthcare Professionals

In line with the PRACs recommendation healthcare professionals are advised to

- Use the medicine at the lowest effective dose for as short a time as possible.
- Restrict use in the elderly.

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- 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.
- Avoid use 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.

For more information please visit **www.ema.europa.eu**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on hydroxyzine containing medicines. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.

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