PRAC recommends new measures to minimise cardiovascular side effects of hydroxyzine containing medicines (Atarax®)

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Information on hydroxyzine containing products

- Hydroxyzine containing products are approved for various uses, including relief of anxiety disorders, premedication before surgical procedures, relief of urticaria or various other conditions associated with pruritus (itching), and treatment of sleep disorders.
- In Malta hydroxyzine is marketed as Atarax® with the following products being authorised for use locally;

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

Information from the European Medicines Agency about the safety concern

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review on hydroxyzine following concerns over the risk of possible effects on heart rhythm and found 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.

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.
- 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.

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- 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.

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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