Recommendation to restrict the use of Trimetazidine-containing medicinal products

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Information on Trimetazidine

Trimetazidine is a cardiac (heart) therapy medicinal product (ATC code C01EB15) which is used;

1) To prevent angina attacks
2) As a 'metabolic agent' (a medicine which has an effect on metabolism). It is believed to protect against myocardial ischaemia (reduced blood supply to the heart muscle) by increasing the rate at which glucose is broken down.
3) To treat the symptoms of vertigo (a spinning sensation) and tinnitus (ringing sensation in the ears), and to treat reduced vision and visual field disturbances (unclear or disturbed vision) due to problems affecting the blood vessels.

Medicines containing trimetazidine have been available since the 1970s and are currently marketed in many EU member states including Malta. Medicinal products authorised in Malta which contain Trimetazidine are marketed as Vastarel, Vastarel MR and Trimetazidine LPH.

Information from European Medicines Agency about the safety concern

The review on this medicine was initiated by France, because of concerns that the efficacy of trimetazidine was not sufficiently demonstrated. Reports regarding the occurrence of movement disorders such as Parkinsonian symptoms, restless leg syndrome, tremors and gait instability associated with the medicine were reviewed. Although patients usually recovered fully from their side-effects within four months after treatment with trimetazidine was discontinued, the Committee recommended new contraindications and warnings to reduce and manage the possible risk of movement disorders associated with the use of this medicine.

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In Malta

For Healthcare Professionals

- The European Medicines Agency has recommended restricting the use of trimetazidine-containing medicines in the treatment of patients with angina pectoris to second-line, add-on therapy. For all other indications the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of these medicines were not sufficiently demonstrated and did not outweigh the risks. The CHMP therefore recommended their deletion from the marketing authorisation.
- Doctors should no longer prescribe trimetazidine for the treatment of patients with tinnitus, vertigo or disturbances in vision. Patients who are taking trimetazidine in these indications should discuss alternatives with their doctor.
- Doctors can continue to prescribe trimetazidine for the treatment of angina pectoris, but only as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line anti-anginal therapies.
- Doctors are advised not to prescribe the medicine to patients with Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome orother related movement disorders, nor to patients with severe renal impairment.
- Doctors should exercise caution when prescribing trimetazidine to patients with moderate renal impairment and to elderly patients, and consider dose reduction in these patients.
- Trimetazidine should be discontinued permanently in patients who develop movement disorders such as Parkinsonian symptoms. If Parkinsonian symptoms persist for more than four months after discontinuation, a neurologist's opinion should be sought.

There is no need for an urgent change in treatment, but doctors should review their patients' treatment at their next routine appointment.

The CHMP's opinion will be sent to the European Commission for the adoption of a binding decision throughout the European Union.

Advice for patients

- Patients are advised not to stop their medicine abruptly but to speak to their doctors at their next scheduled appointment.

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For more information please see the **press release** and **question-and-answer document** issued by the European Medicines Agency on Trimetazidine-containing medicinal products.

Reporting adverse drug reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Trimetazidine-containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder or their local representatives. ‘

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

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