



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends restricting use of trimetazidine-containing medicines

Restricted indication for patients with stable angina pectoris and deletion of existing indications for treatment of vertigo, tinnitus and vision disturbance

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.

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

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.

The review was initiated by France, mainly because of concerns that the efficacy of trimetazidine was not sufficiently demonstrated. It also looked at reports regarding the occurrence of movement disorders such as Parkinsonian symptoms, restless leg syndrome, tremors and gait instability associated with the medicine. Although patients usually recovered fully 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.

Doctors are advised not to prescribe the medicine to patients with Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome or other 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.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Medicines containing trimetazidine have been available since the 1970s and are currently marketed in Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia and Spain. They are marketed under the invented name Vastarel and other trade names.
3. The review of trimetazidine-containing medicines was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, initiated at the request of France.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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