22 July 2011
EMA/CHMP/581202/2011
Press Office

Press release

European Medicines Agency agrees to recall of Vimpat 15mg/ml syrup

Doctors advised to switch patients to an alternative formulation whenever possible

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed to a recall of Vimpat 15mg/ml syrup because of a quality defect in some batches leading to uneven distribution of the active substance lacosamide in the syrup. Doctors are advised to contact their patients to switch them to Vimpat film coated tablets whenever possible.

Patients are advised not to stop their medication or change the dose without speaking to their doctor.

The marketing authorisation holder for Vimpat is currently preparing the submission of an application for a 10mg/ml syrup for Vimpat to continue to make the medicine available in a liquid formulation. Until this new formulation is authorised in the EU, another 10mg/ml liquid formulation, which is currently approved in the US, may be made available on a named patient basis for those patients who cannot take Vimpat tablets.

Vimpat is used to treat partial-onset seizures (epileptic fits starting from one specific part of the brain) as an add-on to other antiepileptic medicines in patients with epilepsy aged 16 years and older.

The European Medicines Agency was informed by the marketing authorisation holder that a flake-like precipitate was observed in bottles of Vimpat 15mg/ml syrup. The precipitate consists of the active substance lacosamide and is not a contamination.

Further analysis carried out by the company showed that the active substance was not evenly distributed in the syrup, which could lead to patients receiving either too much or too little of the active substance. Although no cases of adverse reactions related to over- or under-dosing have been reported, the marketing authorisation holder, in agreement with the CHMP, has proposed a recall of Vimpat 15mg/ml syrup from the supply chain as a precautionary measure.

Doctors will be receiving a letter in the next few days informing them of the recall and advising them on how to manage patients who are currently on Vimpat 15mg/ml. The recall will be started on 15 September 2011 to allow sufficient time for patients to be switched to suitable alternatives.

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The CHMP has now initiated at the request of the European Commission a review under Article 20 of Regulation (EC) No 726/2004 to determine whether in light of this quality defect the benefits of Vimpat 15mg/ml syrup continue to outweigh its risks and whether the marketing authorisation for this formulation should be maintained, varied, suspended or withdrawn across the European Union.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Vimpat has been authorised in the European Union since 2008. It is available as film-coated tablets, as a solution for intravenous use or as syrup. This review only concerns Vimpat 15mg/ml syrup.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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