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Press Office

Press release

European Medicines Agency recommends discontinuation of Vimpat 15mg/ml syrup

Vimpat 15mg/ml syrup no longer available because of quality defect; other Vimpat presentations remain available for patients with epilepsy

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that Vimpat 15mg/ml syrup should no longer be marketed. The CHMP's recommendation follows the voluntary recall of Vimpat 15mg/ml syrup on 15 September 2011. The recall was initiated because of a quality defect in some batches leading to uneven distribution of the active substance lacosamide in the syrup. As this defect could not be remediated, e.g. by changing storage conditions, the Committee concluded that the benefit of Vimpat 15mg/ml syrup does not outweigh the risk that patients might receive either too much or too little of the active substance, and therefore recommended the permanent discontinuation of Vimpat 15mg/ml syrup.

Patients should not stop taking their current medication or change their dose without speaking to their doctor.

Doctors should contact patients currently on Vimpat 15mg/ml syrup as soon as possible to switch them to Vimpat film-coated tablets whenever possible. For patients who cannot take tablets, it may be possible to obtain the US-approved Vimpat 10mg/ml liquid formulation, which does not have this quality defect, on a named patient basis (An application for a marketing authorisation for this formulation in the European Union has been submitted to the Agency in August 2011 and is currently under review by the CHMP). Otherwise, alternative antiepileptic treatments may have to be considered.

Pharmacists should return any bottles of Vimpat 15mg/ml syrup to their supplier.

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 review of the benefits and risks of Vimpat 15mg/ml syrup started in July 2011. Previously, the Agency had been informed by the marketing authorisation holder that a flake-like precipitate had been observed in bottles of Vimpat 15mg/ml syrup. The precipitate consisted of the active substance

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lacosamide and was 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 the precipitate, the CHMP agreed to the company's proposal to recall Vimpat 15mg/ml syrup from the supply chain on 15 September 2011 as a precautionary measure.

Availability of a liquid formulation is essential for some patients. The Agency has therefore worked with the company to continue to make this important alternative formulation available to patients who need it. The application for a marketing authorisation for a 10mg/ml liquid formulation is currently under review by the CHMP.

The CHMP's opinion has now been forwarded to the European Commission for the adoption of a decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The recall of Vimpat 15mg/ml syrup was agreed in July 2011 and initiated on 15 September 2011.
3. 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.
4. All other opinions and documents adopted by the CHMP at their September 2011 plenary meeting will be published on Friday, 23 September 2011 at 12.00 noon UK time on a dedicated web page.
5. More information on the work of the European Medicines Agency can be found on its website www.ema.europa.eu

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