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Questions and answers on the recall of Vimpat 15mg/ml syrup (lacosamide)

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed to a recall of Vimpat 15 mg/ml syrup, following a quality issue in some batches leading to an uneven distribution of the active substance lacosamide in the syrup. Communication has been issued to healthcare professionals to inform them of the quality problem and the planned recall, and to provide guidance on how to manage patients who are currently on Vimpat 15 mg/ml syrup.

What is Vimpat?

Vimpat is a medicine containing the active substance lacosamide.

Vimpat is an antiepileptic that 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. It can be used in patients with partial-onset seizures with or without secondary generalisation (where the seizure subsequently spreads to the whole brain).

Vimpat has been authorised in the EU since 29 August 2008[1]. Vimpat is available as film coated tablets, as a solution for intravenous use or as syrup. This quality defect only concerned Vimpat syrup.

Why is Vimpat 15 mg/ml syrup being recalled?

On 17 June 2011, the Agency was made aware of a quality defect in several batches of Vimpat 15 mg/ml syrup, in which the syrup was reported to contain flake-like precipitates (small solid particles) of the active substance, lacosamide. It was not a product contamination.

The company carried out an investigation in bottles with precipitate which showed that lacosamide was not evenly distributed in the solution and this could affect the dose of lacosamide that patients receive, leading them to receive too much or too little. An analysis of affected batches showed that this problem could not be remediated. Although, no cases of adverse effects or lack of effect have been reported, the company, as a precaution, proposed to recall all batches of Vimpat 15 mg/ml syrup.

1 Vimpat 15 mg/ml syrup is currently marketed in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Spain, Sweden, the United Kingdom as well as, Norway

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The Committee agreed and discussed alternatives which could be used in patients currently on Vimpat 15 mg/ml syrup, such as Vimpat film coated tablets. The CHMP also noted as an alternative a 10 mg/ml liquid formulation, which does not have this defect and which is currently approved in the United States and may be obtained under certain circumstances.

The company will communicate with healthcare professionals to inform them of the quality problem and the planned recall, and to provide guidance on how to manage patients who are currently on Vimpat 15 mg/ml syrup. It was agreed that the product should be recalled on 15 September 2011 in order to allow enough time for patients to be switched to suitable alternatives.

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 these quality defects the benefits of Vimpat 15 mg/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 (EU).

What are the recommendations for pharmacists and doctors?

- Doctors should not start any new patients on Vimpat 15 mg/ml syrup.
- Doctors should contact patients on Vimpat 15mg/ml syrup as soon as possible in order to switch them to an alternative treatment.
- Patients on Vimpat 15 mg/ml syrup should be switched to Vimpat film coated tablets whenever possible. For patients who cannot take the tablets, it may be possible to obtain the US approved Vimpat 10 mg/ml liquid formulation on a named patient basis or alternative antiepileptic treatment may have to be considered.
- For patients on doses above 200 mg/day of Vimpat the dose must gradually be tapered down as per official recommendations.
- Pharmacists should refer any patients on Vimpat 15 mg/ml syrup to their doctor.
- While Vimpat 15 mg/ml syrup remains available pharmacists should inspect each bottle to ensure they are free from precipitate.
- Pharmacists should return all bottles of Vimpat 15 mg/ml syrup to their supplier effective as of 15 September 2011

What are the recommendations for patients?

- Patients should note that so far no cases of adverse effects or lack of effect due to the quality defect of Vimpat 15 mg/ml syrup have been reported and the recall is therefore a precautionary measure.
- Patients should not stop taking their current medication or change their dose, without medical supervision.
- Patients currently using Vimpat 15 mg/ml syrup should speak to their doctor to discuss their treatment.
- Patients who have any questions should speak to their doctor or pharmacist.

The current European public assessment report for Vimpat can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.