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Press Office

Press release

European Medicines Agency recommends restricting use of tolperisone medicines

Benefit-risk profile for oral tolperisone considered positive only for adults with post-stroke spasticity and negative for injectable tolperisone

The European Medicines Agency has recommended restricting the use of tolperisone, a muscle relaxant authorised to treat a variety of different conditions, including spasticity due to neurological disorders and muscle spasms associated with diseases of the spine and large joints in several European Union countries since the 1960s.

The review by the Agency's Committee for Medicinal Products for Human Use (CHMP) was initiated by Germany following concerns over several hypersensitivity reactions reported post marketing and insufficiently demonstrated efficacy in some indications. Taking into account that the risk of hypersensitivity reactions is more significant than previously identified and due to uncertainties in relation to its efficacy in the different indications, the Committee concluded that the benefits of tolperisone outweighed its risks only in the treatment of adults with post-stroke spasticity and only when used as an oral formulation.

Doctors should stop prescribing tolperisone for any other indication than post-stroke spasticity in adults. They should also no longer use injectable tolperisone.

Patients currently using tolperisone for any other indication or using injectable tolperisone should speak to their doctor at their next routine appointment so they can switch to an appropriate alternative treatment.

Patients should be made aware of the possibility of developing hypersensitivity reactions during treatment with tolperisone. They should stop treatment with tolperisone and speak to their doctor if they experience symptoms such as flushing, rash, severe itching of the skin (with raised lumps), wheezing, difficulty breathing, difficulty in swallowing, fast heartbeat, low blood pressure or fast decrease in blood pressure.

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

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Tolperisone-containing products are currently approved in the following EU countries: Austria, Bulgaria, Cyprus, Czech Republic, Germany, Hungary, Latvia, Lithuania, Poland, Romania and Slovak Republic.
3. The review of tolperisone-containing medicines was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, initiated at the request of Germany.
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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