



The European Agency for the Evaluation of Medicinal Products
Post-authorisation evaluation of medicines for human use

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EMEA PUBLIC STATEMENT ON THE LIFTING OF THE SUSPENSION OF THE MARKETING AUTHORISATION FOR TOLCAPONE (Tasmar)

At its April 2004 meeting the EMEA's scientific committee, the CPMP, recommended lifting the suspension of the Marketing Authorisation (MA) for tolcapone (Tasmar) following the review of the available clinical evidence.

Tolcapone is a catechol-O-methyltransferase (COMT) inhibitor medicine developed for use in Parkinson's disease.

The European Commission has suspended the Marketing Authorisation for Tasmar throughout the European Union since November 1998, following concerns over hepatotoxicity and Neuroleptic Malignant Syndrome. During the period of suspension, the Marketing Authorisation Holder has submitted clinical safety data and, in July 2003, the results of a new clinical study.

Having reviewed all available clinical evidence, the CPMP considered that:

- In specific conditions of use as demonstrated during a study of short duration (three weeks), there was evidence of efficacy for tolcapone over entacapone in the control of motor fluctuations in patients with advanced Parkinson's disease;
- There is better insight and understanding of safety concerns relating to hepatitis and neuroleptic malignant-like syndrome, with respect to their incidence and the means to prevent their occurrence;

On the basis of these considerations the Committee recommended the following changes to the product information as well as the conditions regarding supply and use of Tasmar:

- More stringent liver function monitoring and closer attention to the monitoring of possible signs and symptoms of underlying liver disease;
- Contraindication in patients with severe dyskinesia or with a previous history of Neuroleptic Malignant Syndrome Symptom Complex (NMS) and /or non-traumatic Rhabdomyolysis or hyperthermia;
- Change in legal status of Tasmar to restrict prescription by physicians experienced in the management of advanced Parkinson's disease.

The product information has been revised accordingly, including a restriction of the therapeutic indication to patients "who failed to respond to or are intolerant of other COMT inhibitors", as well as additional contraindications, warnings and precautions.

Therefore, the CPMP concluded that the balance of benefits and risks for tolcapone to be favourable and consequently, on 22 April 2004 recommended the lifting of the suspension of the Community Marketing Authorisation for the medicinal product Tasmar (tolcapone).

The safe use of Tasmar will be closely monitored by the CPMP.

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