



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/388409/2014
EMA/H/C/00132

EPAR summary for the public

Tasmar

tolcapone

This is a summary of the European public assessment report (EPAR) for Tasmar. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tasmar.

What is Tasmar?

Tasmar is a medicine that contains the active substance tolcapone. It is available as tablets (100 mg and 200 mg).

What is Tasmar used for?

Tasmar is used to treat patients with Parkinson's disease. Parkinson's disease is a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Tasmar is used together with other standard treatments for Parkinson's disease (either a combination of levodopa and benserazide or a combination of levodopa and carbidopa) when the patients have 'fluctuations' towards the end of the period between two doses of their standard combination. Fluctuations are linked with a reduction in the effects of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and immobile. Tasmar is only used when patients do not respond, or cannot take other medicines of the same type.

The medicine can only be obtained with a prescription.

How is Tasmar used?

Tasmar treatment should only be prescribed and supervised by a doctor who has experience in the management of advanced Parkinson's disease.

Tasmar is always given with levodopa and benserazide or with levodopa and carbidopa. The recommended dose is 100 mg three times a day. The first dose of the day of Tasmar should be taken



together with the first daily dose of the levodopa preparation, and subsequent doses of Tasmar should be given approximately 6 and 12 hours later. The tablets should be swallowed whole.

When patients add Tasmar to their existing anti Parkinson's disease medication, they need to be made aware that they may experience some of the side effects of levodopa, although these can often be reduced by lowering the dose of levodopa. The dose of Tasmar may be increased to 200 mg three times a day but only when the benefit expected outweighs the risk of liver injury. If after three weeks, no substantial benefit has been seen, treatment with Tasmar should be stopped.

Doctors should check the patient's liver before starting treatment with Tasmar and then regularly during treatment. Treatment should be stopped in patients who develop liver problems.

How does Tasmar work?

In patients with Parkinson's disease, the cells in the brain that produce the neurotransmitter dopamine begin to die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. The active substance in Tasmar, tolcapone, works to restore the levels of dopamine in the parts of the brain that control movement and coordination. It only works when it is taken with levodopa, a copy of the neurotransmitter dopamine that can be taken by mouth. Tolcapone blocks an enzyme that is involved in the breakdown of levodopa in the body called catechol-O-methyl transferase (COMT). As a result, levodopa remains active for longer. This helps to improve the signs and symptoms of Parkinson's disease, such as stiffness and slowness of movement.

How has Tasmar been studied?

Tasmar was originally studied in a total of 594 patients, in two 13-week studies and one six-week study. All of the studies compared Tasmar with placebo (a dummy treatment) when they were added to the patient's existing medication (levodopa and either carbidopa or benserazide). The main measure of effectiveness was how long the patients spent in the 'off' or in the 'on' state.

Tasmar has also been studied in a 'switch' study in 150 patients. These patients were already receiving a combination of levodopa and entacapone (another medicine that blocks COMT). The study compared continuing to take entacapone with switching to Tasmar. The main measure of effectiveness was the number of patients with an increase in 'on' time of one hour or more, during the three weeks following the switch.

What benefit has Tasmar shown during the studies?

The initial studies showed that Tasmar was more effective than placebo. There was a reduction of about 20 to 30% in 'off' time in patients taking Tasmar.

In the switch study, more patients responded to Tasmar (53%; 40 out of 75) than to entacapone (43%; 32 out of 75).

What is the risk associated with Tasmar?

The most common side effects with Tasmar (seen in more than 1 patient in 10) are nausea (feeling sick), loss of appetite, diarrhoea, dyskinesia (uncontrollable movements), dystonia (muscle spasms), headache, dizziness, sleep disorders, excessive dreaming, somnolence (sleepiness), confusion, hallucination (seeing things that are not there) and orthostatic complaints (dizziness on standing). Tasmar can cause liver injury, which can be fatal in rare cases. Doctors should monitor patients very carefully during treatment. For the full list of all side effects reported with Tasmar, see the package leaflet.

Tasmar must not be used in patients with:

- signs of liver disease or increased liver enzymes;
- phaeochromocytoma (a tumour of the adrenal gland);
- a history of neuroleptic malignant syndrome (a dangerous nervous disorder usually caused by antipsychotic medicines), rhabdomyolysis (breakdown of muscle fibres) or hyperthermia (heat stroke);
- severe dyskinesia.

Tasmar must also not be used in patients who are being treated with medicines known as non-selective monoamine oxidase (MAO) inhibitors.

For the full list of restrictions see the package leaflet.

Why has Tasmar been approved?

The CHMP decided that Tasmar's benefits are greater than its risks in combination with levodopa/benserazide or levodopa/carbidopa for use in patients with levodopa-responsive idiopathic Parkinson's disease and motor fluctuations, who failed to respond to or are intolerant of other COMT inhibitors. The Committee recommended that Tasmar be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Tasmar?

A risk management plan has been developed to ensure that Tasmar is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tasmar, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tasmar

The European Commission granted a marketing authorisation valid throughout the European Union for Tasmar on 27 August 1997.

The full EPAR for Tasmar can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Tasmar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2014.