



LES LABORATOIRES SERVIER

October 2015

Direct Healthcare Professional Communication

Trivastal / Pronoran /Clarium / Trivastan (piribedil) oral formulation: Restriction of the indication to treatment of Parkinson's disease

Dear Healthcare professional,

Les Laboratories Servier in agreement with the Medicines Authority would like to inform you about the restriction of the indication of piribedil oral formulation to the treatment of Parkinson's disease.

Summary

Piribedil (oral formulation) is now only indicated in the treatment of Parkinson's disease:

- *either as single-agent therapy (treatment of essential forms with tremor),*
- *or in combination with levo-dopa, from the outset or secondarily, in particular in forms with tremor.*

Piribedil (oral formulation) should no longer be prescribed or dispensed for indications other than Parkinson's disease:

- *Ancillary symptomatic treatment of chronic cognitive and neurosensory pathological deficiency in the elderly (excluding Alzheimer's disease and other forms of dementia),*
- *Ancillary treatment of intermittent claudication in chronic occlusive arterial disease of the legs (stage 2),*
- *Ischemic symptoms in ophthalmology*

Further information

The MAH's decision is a consequence of the regulatory actions in France and other concerned EEA member states such as Poland and Luxembourg to restrict indications to Parkinson's disease.

Following the benefit-risk reassessment of piribedil in France, the French regulatory agency in June 2013 concluded that the benefit/risk balance of piribedil only remains positive in the treatment of Parkinson's disease either as monotherapy or in combination with dopatherapy from the outset or secondarily.

It was concluded that for all other indications the efficacy of piribedil is not sufficiently documented according to current guidelines and methodology.

Following the review of pharmacovigilance data in November 2014, the CMDh (coordination Group for Mutual Recognition and Decentralized Procedures – Human) has supported the decision to restrict of the indication of piribedil oral formulation to the treatment of Parkinson's disease.

Recommendations

- o Doctors should review their patients' treatment at the next opportunity in order to discontinue treatment with piribedil (oral formulations) if prescribed in the concerned indications and consider alternative treatments;
- o Pharmacists should refer patients to their treating physician.

Merci d'adresser toute correspondance au :

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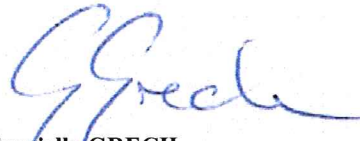
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