28 January 2016
EMA/CHMP/23731/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rasagiline Mylan

rasagiline

On 28 January 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rasagiline Mylan, intended for the treatment of idiopathic Parkinson's disease. The applicant for this medicinal product is MYLAN S.A.S.

Rasagiline Mylan will be available as 1-mg tablets. The active substance of Rasagiline Mylan is rasagiline, a selective monoamine oxidase type B inhibitor (MAO-B) (ATC code: N04BD02). MAO inhibitors in Parkinson's disease inhibit MAO-B in the human brain thereby decreasing the oxidative deamination of both endogenous dopamine and dopamine produced from exogenous levodopa. Thus dopamine levels are increased and dopaminergic function is improved

Rasagiline Mylan is a generic of Azilect, which has been authorised in the EU since 24 February 2005. Studies have demonstrated the satisfactory quality of Rasagiline Mylan, and its bioequivalence to the reference product Azilect. A question and answer document on generic medicines can be found here.

The full indication is: "Treatment of idiopathic Parkinson's disease (PD) as monotherapy (without levodopa) or as adjunct therapy (with levodopa) in patients with end of dose fluctuations".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact