28 January 2016
EMA/CHMP/18049/2016
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Amlodipine-Valsartan Mylan

amlodipine / valsartan

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 Amlodipine-Valsartan Mylan, intended for the treatment of essential hypertension. The applicant for this medicinal product is MYLAN S.A.S.

Amlodipine-Valsartan Mylan will be available as 5 mg / 160 mg, 5 mg / 80 mg and 10 mg / 160 mg Film-coated tablet. The active substances of Amlodipine-Valsartan Mylan are amlodipine / valsartan, an agent acting on the renin-angiotensin system and calcium channel blockers. The ATC code is C09DB01 angiotensin II antagonists, combinations.

Amlodipine-Valsartan Mylan is a generic of Exforge, which has been authorised in the EU since 17 Jan 2007. Studies have demonstrated the satisfactory quality of Amlodipine-Valsartan Mylan, and its bioequivalence to the reference product Exforge. A question and answer document on generic medicines can be found here.

The full indication is: "Treatment of essential hypertension.Amlodipine/Valsartan Mylan is indicated in adults whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.

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

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