EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2013
EMA/CHMP/397194/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Imprida

Amlodipine/valsartan

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Imprida. The marketing authorisation holder for these medicinal products is Novartis Europharm Ltd. They may request a re- examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new contraindication as follows:
" Concomitant use of angiotensin receptor antagonists (ARB) - including valsartan - or of angiotensin converting enzyme (ACE) inhibitors with aliskiren in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73m^2)."

Detailed conditions for the use of these products will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Imprida will be as follows[2]:

- Hypersensitivity to the active substances, to dihydropyridine derivatives, or to any of the excipients listed in section 6.1.
- Severe hepatic impairment, biliary cirrhosis or cholestasis.
- Severe renal impairment (glomerular filtration rate (GFR) <30 ml/min/1.73 m^2) and patients undergoing dialysis.
- **Concomitant use of angiotensin receptor antagonists (ARB) - including valsartan - or of angiotensin converting enzyme (ACE) inhibitors with aliskiren in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73m^2) (see sections 4.4 and 4.5).**

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended contraindication.

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- Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
- Severe hypotension.
- Shock (including cardiogenic shock).
- Obstruction of the outflow tract of the left ventricle (e.g. hypertrophic obstructive cardiomyopathy and high grade aortic stenosis).
- Haemodynamically unstable heart failure after acute myocardial infarction.