



27 June 2013
EMA/CHMP/397292/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Dafiro HCT

Amlodipine/valsartan/hydrochlorothiazide

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 Dafiro HCT. The marketing authorisation holder for the 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/1.73m²)."

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 Dafiro HCT will be as follows²:

- Hypersensitivity to the active substances, to other sulphonamide derivatives, to dihydropyridine derivatives, or to any of the excipients.
- Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
- Hepatic impairment, biliary cirrhosis or cholestasis.
- Severe renal impairment (GFR <30 ml/min/1.73 m²), anuria 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**

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.



diabetes mellitus or renal impairment (GFR <60 ml/min/1.73m²) (see sections 4.4 and 4.5).

- Refractory hypokalaemia, hyponatraemia, hypercalcaemia, and symptomatic hyperuricaemia.
- 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.