EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2013
EMA/CHMP/388323/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Karvezide

Irbesartan / 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 Karvezide. The marketing authorisation holder for this medicinal product is Sanofi-Aventis Groupe. 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:
"Co-administration of Karvezide with aliskiren-containing medicines in patients with diabetes or with moderate to severe renal impairment (glomerular filtration rate (GFR) < 60 ml/min/1.73 m2)."

Detailed conditions for the use of this product 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 Karvezide will be as follows[2]:

- " Hypersensitivity to the active substances or to any of the excipients listed in section 6.1, or to other sulfonamide-derived substances (hydrochlorothiazide is a sulfonamide-derived substance)
- Second and third trimesters of pregnancy (see sections 4.4 and 4.6)
- Severe renal impairment (creatinine clearance < 30 ml/min)
- Refractory hypokalaemia, hypercalcaemia
- Severe hepatic impairment, biliary cirrhosis and cholestasis
- **Co-administration of Karvezide with aliskiren-containing medicines in patients with diabetes or with moderate to severe renal impairment (glomerular filtration rate (GFR) <60 ml/min/1.73 m²) (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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