

aliskiren/hydrochlorothiazide in treatment of essential hypertension is considered positive for the treatment of hypertension in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone, and as replacement therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination.

A risk management plan was submitted. The CHMP, having considered the data submitted, was of the opinion that:

routine pharmacovigilance was adequate to monitor the safety of the product

AND

no additional risk minimisation activities were required beyond those included in the product information.

Recommendation

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considered by consensus that the risk-benefit balance of Rasilez HCT in the treatment of essential hypertension in adults, when Rasilez HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone or when indicated as a substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination, was favourable and therefore recommended the granting of the marketing authorisation.

Medicinal Product no longer authorised