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Public statement

Rasilez HCT

Withdrawal of the marketing authorisation in the European Union

On 20 December 2021, the European Commission withdrew the marketing authorisation for Rasilez HCT (aliskiren / hydrochlorothiazide) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Noden Pharma DAC, which notified the European Commission of its decision to permanently discontinue the marketing of the product in the EU for commercial reasons.

Rasilez HCT was granted marketing authorisation in the EU on 16 January 2009 for the treatment of essential hypertension. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2013. It was then granted unlimited validity in 2018. The product had not been marketed in the EU since 16 January 2009.

The European Public Assessment Report (EPAR) for Rasilez HCT will be updated to indicate that the marketing authorisation is no longer valid.

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