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Public statement

Budesonide/Formoterol Teva Pharma B.V.

Withdrawal of the marketing authorisation in the European Union

On 16 December 2016, the European Commission withdrew the marketing authorisation for Budesonide/Formoterol Teva Pharma B.V. (budesonide / formoterol) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva Pharma B.V., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Budesonide/Formoterol Teva Pharma B.V. was granted marketing authorisation in the EU on 19 November 2014 for treatment of asthma. The marketing authorisation was initially valid for a 5-year period. Budesonide/Formoterol Teva Pharma B.V. was of DuoResp Spiromax, which is marketed in several EU countries.

The European Public Assessment Report (EPAR) for Budesonide/Formoterol Teva Pharma B.V. will be updated accordingly to indicate that the marketing authorisation is no longer valid.

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