02 July 2019
EMA/284088/2019
EMEA/H/C/004267

Public statement

Airexar Spiromax

Withdrawal of the marketing authorisation in the European Union

On 15 April 2019, the European Commission withdrew the marketing authorisation for Airexar Spiromax (salmeterol / fluticasone propionate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Airexar Spiromax was granted marketing authorisation in the EU on 18 August 2016 for the treatment of asthma and COPD.

Airexar Spiromax was a duplicate application to Aerivio Spiromax, which is marketed in several EU countries.

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Public Assessment Report (EPAR) for Airexar Spiromax will be updated to indicate that the marketing authorisation is no longer valid.

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