



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Pramipexole Accord (pramipexole)

Withdrawal of the marketing authorisation in the European Union

On 13 April 2022, the European Commission withdrew the marketing authorisation for Pramipexole Accord (pramipexole) in the European Union (EU).

The withdrawal was at the request of the marketing authorisation holder, Accord Healthcare S.L.U., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pramipexole Accord was granted marketing authorisation in the EU on 30 September 2011 for the treatment of idiopathic Parkinson's disease and restless legs syndrome. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2016.

Pramipexole Accord is a generic medicine of Mirapexin. There are other generic medicinal products of Mirapexin authorised and marketed in the EU.

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Public Assessment Report (EPAR) for Pramipexole Accord will be updated to indicate that the marketing authorisation is no longer valid.

