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Public statement

Nitisinone MDK (nitisinone)

Withdrawal of the marketing authorisation in the European Union

On 31 March 2023, the European Commission withdrew the marketing authorisation for Nitisinone MDK (nitisinone) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, MendeliKABS Europe Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product in the EU for commercial reasons.

Nitisinone MDK was granted marketing authorisation in the EU on 24 August 2017 for the treatment of hereditary tyrosinaemia type 1 (HT-1). The marketing authorisation was initially valid for a 5-year period. It was granted unlimited validity in 2022.

Nitisinone MDK is a generic medicine of Orfadin. There are other generic medicinal products of Orfadin authorised and marketed in the EU.

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Public Assessment Report (EPAR) for Nitisinone MDK will be updated to indicate that the marketing authorisation is no longer valid.

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