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Public statement

Kolbam

Withdrawal of the marketing authorisation in the European Union

On 13 July 2020, the European Commission withdrew the marketing authorisation for Kolbam (cholic acid) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Retrophin Europe Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Kolbam was granted marketing authorisation in the EU on 04 April 2014 for treatment of inborn errors of primary bile acid synthesis. The marketing authorisation was initially valid for a 5-year period.

Patients currently treated with Kolbam will be transitioned to alternative treatments.

The European Public Assessment Report (EPAR) for Kolbam will be updated to indicate that the marketing authorisation is no longer valid.

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