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Public statement

Topotecan Actavis

Withdrawal of the marketing authorisation in the European Union

On 15 January 2019, the European Commission withdrew the marketing authorisation for Topotecan Actavis (topotecan) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Actavis Group PTC ehf, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Topotecan Actavis was granted marketing authorisation in the EU on 24 July 2009 for treatment of small-cell lung cancer and carcinoma of the cervix. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2014. The product had not been marketed in the EU since 2017.

Topotecan Actavis is a generic medicine of Hycamtin. There are other generic medicinal products of Hycamtin authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Topotecan Actavis will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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