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Public statement

Ulipristal Acetate Gedeon Richter

Withdrawal of the marketing authorisation in the European Union

On 14 June 2021, the European Commission withdrew the marketing authorisation for Ulipristal Acetate Gedeon Richter (ulipristal acetate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Gedeon Richter Plc., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Ulipristal Acetate Gedeon Richter was granted marketing authorisation in the EU on 27 August 2018 for the treatment of uterine fibroids. The marketing authorisation was initially valid for a 5-year period.

Ulipristal Acetate Gedeon Richter was a duplicate application to Esmya, which is marketed in several EU countries.

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Report (EPAR) for Ulipristal Acetate Gedeon Richter will be updated to indicate that the marketing authorisation is no longer valid.

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