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Public statement

Zoledronic acid Teva Pharma

Withdrawal of the marketing authorisation in the European Union

On 18 January 2018 the European Commission withdrew the marketing authorisation for Zoledronic acid Teva Pharma (zoledronic acid) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Zoledronic acid Teva Pharma was granted marketing authorisation in the EU on 16 August 2012 for treatment of osteoporosis. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2017.

Zoledronic acid Teva Pharma is a generic medicine of Aclasta. There are other generic medicines of Aclasta authorised and marketed in the EU.

The European public assessment report (EPAR) for Zoledronic acid Teva Pharma will be updated to reflect the fact that the marketing authorisation is no longer valid.

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