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Public statement

Zoledronic acid Teva Generics

Withdrawal of the marketing authorisation in the European Union

On 13 July 2015 the European Commission withdrew the marketing authorisation for Zoledronic acid Teva Generics (zoledronic acid) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva Generics B.V, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Zoledronic acid Teva Generics was granted marketing authorisation in the EU on 27 March 2014 for the treatment of osteoporosis and Paget's disease of the bone. The marketing authorisation was initially valid for a 5-year period.

Zoledronic acid Teva Generics is a generic medicine of Aclasta. Zoledronic acid Teva Generics was a duplicate application to Zoledronic acid Teva Pharma, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Zoledronic acid Teva Pharma.

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for Zoledronic acid Teva Generics will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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