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Public statement

Zalviso (sufentanil)

Withdrawal of the marketing authorisation in the European Union

On 5 August 2022, the European Commission withdrew the marketing authorisation for Zalviso (sufentanil) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, FGK Representative Service GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Zalviso was granted marketing authorisation in the EU on 18 September 2015 for the management of acute moderate to severe post-operative pain. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2020.

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European Public Assessment Report (EPAR) for Zalviso will be updated to indicate that the marketing authorisation is no longer valid.

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