12 December 2019
EMA/CHMP/670824/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Akynzeo

fosnetupitant / palonosetron

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Akynzeo (fixed combination of fosnetupitant [pro-drug of netupitant] and palonosetron). The marketing authorisation holder for this medicinal product is Helsinn Birex Pharmaceuticals Limited.

The CHMP adopted a new pharmaceutical form associated with a new strength and a new route of administration as follows:

Akynzeo 235 mg/0.25 mg powder for concentrate for solution for infusion for intravenous use

For information, the full presentations for Akynzeo will be as follows:

Akynzeo 300 mg / 0.50 mg hard capsule, for oral use

Akynzeo 235 mg / 0.25 mg powder for concentrate for solution for infusion for intravenous use

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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