EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2017
EMA/CHMP/97358/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Varuby

rolapitant

On 23 February 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Varuby, intended for prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. The applicant for this medicinal product is Tesaro UK Limited.

Varuby will be available as 90-mg film-coated tablets. The active substance of Varuby is rolapitant, an antiemetic (ATC code: A04AD14). Chemotherapy can cause the body to release substance P which attaches to nerve cells in the brain's vomiting centre and makes the patient feel sick or be sick. Rolapitant blocks substance P from attaching to these nerve cells and this helps prevent nausea and vomiting.

The benefits with Varuby are its ability to reduce emetic episodes and the use of rescue medicines in the delayed phase (after 24 to 120 hours) in patients treated with highly or moderately emetogenic chemotherapy. The most common side effects are headache, constipation and fatigue.

The full indication is: "Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Varuby is given as part of combination therapy".

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

Medicinal product no longer authorised

[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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