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EPAR summary for the public

Varuby

rolapitant

This is a summary of the European public assessment report (EPAR) for Varuby. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Varuby.

For practical information about using Varuby, patients should read the package leaflet or contact their doctor or pharmacist.

What is Varuby and what is it used for?

Varuby is a medicine used to prevent nausea (feeling sick) and vomiting in adult cancer patients who are receiving chemotherapy (medicines to treat cancer). Different chemotherapy medicines produce different degrees of nausea and vomiting, and Varuby is used in patients receiving highly or moderately emetogenic (vomit-inducing) chemotherapy.

Varuby acts against delayed nausea and vomiting (when the symptoms occur 24 hours or more after the cancer treatment) and is given with other medicines that help control more immediate nausea and vomiting.

Varuby contains the active substance rolapitant.

How is Varuby used?

Varuby can only be obtained with a prescription and is available as 90-mg tablets. Two tablets are swallowed on the first day of each cycle of chemotherapy, 2 hours or less before chemotherapy starts. Varuby is given with dexamethasone and a 5-HT_3 receptor antagonist (two other types of medicine to prevent nausea and vomiting) but how these are given depends on the type of chemotherapy.

For further information, see the summary of product characteristics (also part of the EPAR).

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How does Varuby work?

The active substance in Varuby, rolapitant, works by blocking neurokinin-1 (NK1) receptors. Chemotherapy can release a substance in the body (substance P) which attaches to these receptors and stimulates delayed nausea and vomiting. By blocking the receptors, Varuby can prevent this effect. When given with medicines that work by other mechanisms to prevent immediate nausea and vomiting, Varuby can help provide prolonged control against these symptoms after chemotherapy.

What benefits of Varuby have been shown in studies?

In two main studies, Varuby was more effective than placebo (a dummy treatment) in preventing delayed nausea and vomiting after highly emetogenic chemotherapy. In both studies, one involving 532 patients and the other involving 555 patients, participants also received dexamethasone and granisetron (a 5-HT_3 receptor antagonist). Adding the results from both studies together, there was no nausea and vomiting in the period from 24 to 120 hours after chemotherapy in 71% of patients (382 out of 535) given Varuby, while the figure with placebo was 60% (322 out of 535 patients).

Varuby was also more effective than placebo in a third main study when used with dexamethasone and granisetron in patients given moderately emetogenic chemotherapy. There was no delayed nausea and vomiting in 71% of patients given Varuby (475 of 666) compared with 62% of those given placebo (410 of 666).

What are the risks associated with Varuby?

The most common side effects with Varuby (which may affect between 1 and 2 people in 100) are tiredness and headache. Patients taking Varuby must not take St John's wort (a herbal medicine for mild depression) as this can reduce the effect of Varuby.

For the full list of all side effects and restrictions with Varuby, see the package leaflet.

Why is Varuby approved?

Varuby produced an improvement in the control of delayed nausea and vomiting when added to other standard treatments. In addition, any side effects were manageable and were similar to those usually observed with medicines for nausea and vomiting. Although a number of medicines are approved in the EU for management of chemotherapy-associated nausea and vomiting significant numbers of patients still experience it, and management of nausea in particular remains a challenge. Overall, therefore, Varuby's benefits are greater than its risks and it has been recommended for approval for use in the EU.

What measures are being taken to ensure the safe and effective use of Varuby?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Varuby have been included in the summary of product characteristics and the package leaflet.

Other information about Varuby

The European Commission granted a marketing authorisation valid throughout the European Union for Varuby on 20 April 2017.

The full EPAR for Varuby can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Varuby, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.