Zorginstituut Nederland

Rolapitant (Varuby®) for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 17 April 2018

Zorginstituut Nederland has carried out an assessment of the medicinal product rolapitant (Varuby®), whereby they came to the following conclusion.

In a letter dated 15 January 2018 (CIBG-18-05659), the Ministry of Health, Welfare and Sport (VWS) asked the *Zorginstituut* to carry out an assessment of whether rolapitant (Varuby®) is interchangeable with a medicinal product currently included in the Medicine Reimbursement System (GVS). The *Zorginstituut*, advised by the Scientific Advisory Committee (WAR), has now completed this assessment.

The manufacturer has asked for inclusion of the product on List 1A of the Health Insurance Decree.

Rolapitant is registered for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Rolapitant is given as part of a combination therapy with dexamethasone and a 5-HT_3 receptor antagonist. Rolapitant is available as a 90-mg film-coated tablet. The recommended dose is: 180 mg on day 1 of each chemotherapy cycle.

Outcome of the assessment
The considerations in the pharmacotherapeutic report show that, based on indirect comparisons of patients treated with high and moderate emetogenic chemotherapy, the favourable and unfavourable effects of rolapitant and aprepitant (both are NK1-antagonists), added to a 5-HT_3 antagonist and dexamethasone, appear to be largely comparable.

The GVS report concludes that, based on the criteria for interchangeability, rolapitant is interchangeable with aprepitant (Emend®). Aprepitant has already been included in the GVS on List 1B. Based on the above, rolapitant (Varuby®) can be placed on List 1A in a new cluster together with aprepitant.

Standard dose
No DDD has been established for rolapitant. The World Health Organisation (WHO) established a DDD of 95 mg for aprepitant. They calculated the average of the recommended dose over the three days per chemotherapy cycle on which aprepitant should be given (on day 1: 125 mg and on days 2 and 3: 80 mg). Similarly to aprepitant, rolapitant is also given as part of a three-day treatment regimen in combination with dexamethasone and a 5-HT_3 receptor antagonist: on day 1: 180 mg, on days 2 and 3 no dose. The standard dose of rolapitant can thus be fixed at 60 mg (the average of the recommended dose over three days).

Advice
Rolapitant can be placed on List 1A in a new cluster with aprepitant. The standard dose of rolapitant can be set at 60 mg per day, that of aprepitant at 95 mg per day.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.