15 September 2022
EMA/CHMP/721208/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Revolade

eltrombopag

On 15 September 2022, 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 Revolade. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension to the existing indication to include use in adults with refractory immune thrombocytopenia (ITP) irrespective of time since initial diagnosis.

For information, the full indication for Revolade will be as follows[2]:

- Revolade is indicated for the treatment of **adult** patients ~~aged 1 year and above~~ with primary immune thrombocytopenia (ITP) ~~lasting 6 months or longer from diagnosis and~~ who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)(see sections 4.2 and 5.1).
- Revolade is indicated for the treatment of **paediatric** patients aged 1 year and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)(see sections 4.2 and 5.1).
- Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy (see sections 4.4 and 5.1).
- Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation (see section 5.1).

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
[2] New text in bold, removed text as strikethrough

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