



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2016
EMA/CHMP/722540/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Revolade

eltrombopag / eltrombopag olamine

On 28 January 2016, 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 Ltd.

The CHMP adopted an extension to the existing indication as follows²:

"Revolade is indicated for ~~adult~~ chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients **aged 1 year and above** who are refractory to other treatments (e.g. corticosteroids, immunoglobulins) (see sections 4.2 and 5.1)".

For information, the full indications for Revolade will be as follows:

"Revolade is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year and above 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

