



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2015
EMA/CHMP/849254/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Nplate romiplostim

On 17 December 2015, 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 Nplate. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

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

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

~~Nplate may be considered as second line treatment for adult non-splenectomised patients where surgery is contra-indicated."~~

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

