

אוקטובר 2025

NPLATE 250 (Romiplostim)
Powder for solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר אנפלייט.

בהודעה זו מצוינים העדכונים המהותיים וההחמרות בלבד.

ההתוויות הרשומות לתכשיר:

Adults:

Nplate is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

Paediatrics:

Nplate is indicated for the treatment of chronic primary immune thrombocytopenia (ITP) in paediatric patients one year of age and older who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

עדכונים בעלון לרופא:

4.8 Undesirable effects

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Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Clinical trials in adult ITP patients examined antibodies to romiplostim and TPO. While 5.7% (60/1,046) and 3.2% (33/1,046) of the subjects were positive for developing binding antibodies to romiplostim and TPO respectively, only 4 subjects were positive for neutralizing antibodies to romiplostim but these antibodies did not cross react with endogenous TPO. Of the 4 subjects, 2 subjects tested negative for neutralizing antibodies to romiplostim at the subject's last timepoint (transient positive) and 2 subjects remained positive at the subject's last timepoint (persistent antibodies). The incidence of pre-existing antibodies to romiplostim and TPO was 3.3% (35/1,046) and 3.0% (31/1,046), respectively.

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As with all therapeutic proteins, there is a potential for immunogenicity. If formation of neutralizing antibodies is suspected, contact the local representative of the Marketing Authorization Holder for antibody testing.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שאתר משרד הבריאות, וניתן לקבלו גם על-
ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
שרות לקוחות: Medison-CS@medison.co.il טלפון: *9274

בברכה,
אמג'ן יורופ בי.וי