

מרץ 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:**

#### 4.4 Special warnings and precautions for use

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##### Thrombotic/thromboembolic complications

Thrombotic/thromboembolic events including deep vein thrombosis, pulmonary embolism, and myocardial infarction have been observed with the use of romiplostim in the ITP population. These events have occurred regardless of platelet count (see section 4.8). Platelet counts above the normal range present a risk for thrombotic/thromboembolic complications. The incidence of thrombotic/thromboembolic events observed in clinical trials was 6.0% with romiplostim and 3.6% with placebo. Caution should be used when administering romiplostim to patients with known risk factors for thromboembolism including but not limited to inherited (e.g. Factor V Leiden) or acquired risk factors (e.g. ATIII deficiency, antiphospholipid syndrome), advanced age, patients with prolonged periods of immobilization, malignancies, contraceptives and hormone replacement therapy, surgery/trauma, obesity and smoking. It is recommended to monitor patients for signs and symptoms of thrombotic/thromboembolic events and treat promptly as per institutional guidance and standard medical practice.

#### 4.8 Undesirable effects (only the updates presented)

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MedDRA system organ class	Very common	Common	Uncommon
Vascular disorders		Flushing Deep vein thrombosis	Deep vein thrombosis Hypotension Peripheral embolism Peripheral ischemia Phlebitis Thrombophlebitis superficial Thrombosis Erythromelalgia

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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](mailto:Medison-CS@medison.co.il) טלפון: \*9274

בברכה,  
אמג'ן יורופ בי. וי