

מאי 2020

NPLATE 250/ 500 (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 לתכשירי אנפלייט. בהודעה זו מצוינים רק עיקרי השינויים שבוצעו.

ההתוויה המאושרות:

Nplate is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients one year of age and older who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

עדכונים בעלון לרופא:

4. CLINICAL PARTICULARS

Pediatric and adult combined dose Calculator

The marketing of Nplate is subject to a risk management plan (RMP) including a 'Pediatric and adult combined dose Calculator.

4.8 Undesirable effects (only the updates presented)

...

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.

In pediatric studies, the incidence of binding antibodies to romiplostim at any time was 9.6% (27/282). Of the 27 subjects, 2 subjects had pre-existing binding non-neutralizing romiplostim antibodies at baseline. Additionally, 2.8% (8/282) developed neutralizing antibodies to romiplostim. A total of 3.9% (11/282) subjects had binding antibodies to TPO at any time during romiplostim treatment. Of these 11 subjects, 2 subjects had pre-existing binding non-neutralizing antibodies to TPO. One subject (0.35%) had a weakly positive postbaseline result for neutralizing antibodies against TPO while on-study (consistently negative for anti-romiplostim antibodies) with a negative result at baseline. The subject showed a transient antibody response for neutralizing antibodies against TPO, with a negative result at the subject's last timepoint tested within the study period.

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: *5634

בברכה,
מאיה ליפסון
רוקחת ממונה