

ינואר 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 הכוללים הוספת התוויה לילדים, הוספת משטר מינון לילדים והחמרות. 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:

4.2 Posology and method of administration

...

The volume of romiplostim to administer is calculated based on body weight, dose required, and concentration of product.

Table 1. Guidelines for calculating individual patient dose and volume of romiplostim to administer

<p><u>Individual patient dose (mcg)</u></p>	<p><u>Individual patient dose (mcg) = weight (kg) × dose in mcg/kg</u></p> <p><u>Actual body weight at initiation of treatment should always be used when calculating initial dose.</u></p> <ul style="list-style-type: none"> • <u>In adults, future dose adjustments are based on changes in platelet counts only.</u> • <u>In pediatric patients, future dose adjustments are based on changes in platelet counts and changes in body weight. Reassessment of body weight is recommended every 12 weeks.</u>
<p><u>If individual patient dose is ≥ 23 mcg</u></p>	<p><u>Reconstitute lyophilized product as described in section 6.6. The resulting concentration is 500 mcg/mL.</u></p> <p><u>Volume to administer (mL) = Individual patient dose (mcg) / 500 mcg/mL</u></p> <p><u>(Round volume to the nearest hundredth mL)</u></p>

<p><u>If individual patient dose is < 23 mcg</u></p>	<p><u>Dilution is required to ensure accurate dosing. Reconstitute lyophilized product and then dilute the product as described in section 6.6. The resulting concentration is 125 mcg/mL.</u></p> <p><u>Volume to administer (mL) = Individual patient dose (mcg) / 125 mcg/mL</u> <u>(Round volume to the nearest hundredth mL)</u></p>
<p><u>Example</u></p>	<p><u>10 kg patient is initiated at 1 mcg/kg of romiplostim.</u></p> <p><u>Individual patient dose (mcg) = 10 kg x 1 mcg/kg = 10 mcg</u></p> <p><u>Because the dose is < 23 mcg, dilution is required to ensure accurate dosing. Reconstitute lyophilized product and then dilute the product as described in section 6.6. The resulting concentration is 125 mcg/mL.</u></p> <p><u>Volume to administer (mL) = 10 mcg / 125 mcg/mL = 0.08 mL</u></p>

...

Method of administration

For subcutaneous use.

After reconstitution of the powder, Nplate solution for injection is administered subcutaneously. The injection volume may be very small. Caution should be used during preparation of Nplate in calculating the dose and reconstitution with the correct volume of sterile water for injection. If the calculated individual patient dose is less than 23 mcg, dilution with preservative-free, sterile, sodium chloride 9 mg/mL (0.9%) solution for injection is required to ensure accurate dosing (see section 6.6). Special care should be taken to ensure that the appropriate volume of Nplate is withdrawn from the vial for subcutaneous administration – a syringe with graduations of 0.01 mL should be used.

Self-administration of Nplate is not allowed for pediatric patients.

4.4 Special warnings and precautions for use

...

Medication errors

Medication errors including overdose and underdose have been reported in patients receiving Nplate, dose calculation and dose adjustment guidelines should be followed. In some pediatric patients, accurate dosing relies on an additional dilution step after reconstitution which may increase the risk for medication errors (see section 4.2).

...

4.8 Undesirable effects *(only the updates presented)*

...

MedDRA system organ class	Very common	Common	Uncommon
Infections and infestations	Upper respiratory tract infection Rhinitis***	Gastroenteritis Pharyngitis*** Conjunctivitis*** Ear infection*** Sinusitis***	Influenza Localized infection Nasopharyngitis

MedDRA system organ class	Very common	Common	Uncommon
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain***	Pulmonary embolism*	Cough Rhinorrhea Dry throat Dyspnea Nasal congestion Painful respiration
Gastrointestinal disorders	Upper abdominal pain***	Nausea Diarrhea Abdominal pain Constipation Dyspepsia	Vomiting Rectal hemorrhage Breath odor Dysphagia Gastro-esophageal reflux disease Hematochezia Mouth hemorrhage Stomach discomfort Stomatitis Tooth discoloration
General disorders and administration site conditions		Fatigue Edema peripheral Influenza like illness Pain Asthenia Pyrexia Chills Injection site reaction Peripheral swelling***	Injection site hemorrhage Chest pain Irritability Malaise Face edema Feeling hot Feeling jittery

* see section 4.4

** Hypersensitivity reactions including cases of rash, urticaria, and angioedema

*** Additional adverse reactions observed in pediatric studies

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