אוגוסט 2024

רופא/ה נכבד/ה

רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

הנדון: Oncaspar 750 U/ml (165-21-36198-00)

Powder for solution for injection/infusion

המאושר להתוויה הבאה:

להלן עיקרי השינויים בעלון לרופא של התכשיר:

4.4 Special warnings and precautions for use

Increased prothrombin time (PT), increased partial thromboplastin time (PTT), hypofibrinogenaemia and antithrombin III decrease can occur in patients receiving pegaspargase. Coagulation parameters should be monitored at baseline and periodically during and after treatment, particularly when other medicinal products with anticoagulant effects (such as acetylsalicylic acid and non-steroidal anti-inflammatory medicinal products) are used simultaneously (see section 4.5), or when concomitant chemotherapy regimen including methotrexate, daunorubicin, corticosteroids is administered. When there is a marked decrease in fibrinogen or antithrombin III (ATIII) deficiency, consider appropriate replacement therapy.

Hepatic veno-occlusive disease (VOD), including severe, life-threatening and potentially fatal cases have been observed in patients treated with Oncaspar in combination with standard chemotherapy, including during the induction phase of multiphase chemotherapy (see section 4.8).

Signs and symptoms of VOD include rapid weight gain, fluid retention with ascites, hepatomegaly, thrombocytopenia and rapid increase of bilirubin. The identification of risk factors like pre-existing liver disease or history of VOD is essential for its prevention. Prompt recognition and appropriate management of VOD remain imperative. Patients who experience this condition should be treated according to standard medical practice.

4.8 Undesirable effects

Adverse reactions reported with Oncaspar therapy

Hepatobiliary disorders: frequency not known: Veno-occlusive disease

Investigations: Very common: antithrombin III decreased, neutrophil count decreased

Hepatobiliary disorders

Alteration of liver parameters is common. A dose-independent rise in serum transaminases, and serum bilirubin is commonly observed.

A rapid weight gain, fluid retention with ascites, hepatomegaly, associated with rapid increase of serum bilirubin and persistent thrombocytopenia might indicate a risk of developing a severe VOD, which if left untreated, can be fatal (see section 4.4).

לשאר העדכונים בעלון יש לעיין בעלון המלא שנשלח לפרסום במאגר התרופות באתר משה"ב. ניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו פארמה בע"מ טלפון: 073-7151111.

בברכה,
צמל ביו פארמה בע"מ