פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

דצמבר 2024

רופא/ה, רוקח/ת נכבד/ה,

אנו מתכבדים להודיעך כי יצא עדכון עלונים לרופא ולצרכן עבור התכשירים:

SOMAVERT® 10 mg, SOMAVERT® 15 mg, SOMAVERT® 20 mg,
SOMAVERT® 25 mg, SOMAVERT® 30 mg

מרכיב פעיל וחוזק:

Each powder vial conatins 10mg or 15mg or 20mg or 25mg or 30mg of pegvisomant.

התוויה:

Treatment of adult patient with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalize IGF-I concentrations or was not tolerated.

להלן העדכונים העיקריים בעלון לרופא:

4.2 Posology and method of administration

…

Assessment of baseline levels of liver enzymes prior to initiation of SOMAVERT

Prior to the start of SOMAVERT, patients should have an assessment of baseline levels of liver tests (LTs) [serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum total bilirubin (TBIL), and alkaline phosphatase (ALP)]. For recommendations regarding initiation of SOMAVERT based on baseline LTs and recommendations for monitoring of LTs while on SOMAVERT, refer to Table A in *Special warnings and precautions for use (4.4)*.

4.4 Special warnings and precautions for use

...

ALT or AST elevations

~~Serum concentrations of alanine aminotransferase (ALT) and aspartate transaminase (AST) should be monitored at four to six week intervals for the first six months of treatment with pegvisomant, or at any time in patients exhibiting symptoms suggestive of hepatitis.~~Prior to the start of SOMAVERT, patients should have an assessment of baseline levels of liver tests [serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum total bilirubin (TBIL), and alkaline phosphatase (ALP)].

Evidence of obstructive biliary tract disease should be ruled out in patients with elevations of ALT and AST or in patients with a prior history of treatment with any somatostatin analogue. Administration of pegvisomant should be discontinued if signs of liver disease persist. For recommendations regarding initiation of SOMAVERT, based on baseline liver tests (LTs) and recommendations for monitoring of liver tests while on SOMAVERT, refer to Table A.

Table A: Recommendations for initiation of SOMAVERT treatment based on baseline LTs and for periodic monitoring of LTs during SOMAVERT treatment

Baseline LT Levels	Recommendations
Normal	• May treat with SOMAVERT. • Serum concentrations of ALT and AST should be monitored at 4- to 6-week intervals for the first 6 months of treatment with SOMAVERT, or at any time in patients exhibiting symptoms suggestive of hepatitis. Monitor quarterly for the next 6 months and then bi-annually for the next year.
Elevated, but less than or equal to 3 times ULN	• May treat with SOMAVERT; however, monitor LTs monthly for at least 1 year after initiation of therapy and then bi-annually for the next year.
Greater than 3 times ULN	• Do not treat with SOMAVERT until a comprehensive workup establishes the cause of the patient's liver dysfunction. • Determine if cholelithiasis or choledocholithiasis is present, particularly in patients with a history of prior therapy with somatostatin analogs. • Based on the workup, consider initiation of therapy with SOMAVERT. • If the decision is to treat, LTs and clinical symptoms should be monitored very closely.

Abbreviations: ALT = alanine aminotransferase; AST = aspartate transaminase; LT = liver test; ULN = upper limit of normal.

If a patient develops LT elevations, or any other signs or symptoms of liver dysfunction while receiving SOMAVERT, the following patient management is recommended (Table B).

Table B. Clinical recommendations based on abnormal liver test results while on SOMAVERT

LT Levels and Clinical Signs/Symptoms	Recommendations
Elevated, but less than or equal to 3 times ULN	• May continue therapy with SOMAVERT. However, monitor LTs monthly to determine if further increases occur.
Greater than 3 but less than 5 times ULN (without signs/symptoms of hepatitis or other liver injury, or increase in serum TBIL)	• May continue therapy with SOMAVERT. However, monitor LTs weekly to determine if further increases occur (see below). • Perform a comprehensive hepatic workup to discern if an alternative cause of liver dysfunction is present.
At least 5 times ULN, or transaminase elevations at least 3 times ULN associated with any increase in serum TBIL (with or without signs/symptoms of hepatitis or other liver injury)	• Discontinue SOMAVERT immediately. • Perform a comprehensive hepatic workup, including serial LTs, to determine if and when serum levels return to normal. • If LTs normalize (regardless of whether an alternative cause of the liver dysfunction is discovered), consider cautious reinitiation of therapy with SOMAVERT, with frequent LT monitoring.
Signs or symptoms suggestive of hepatitis or other liver injury (e.g., jaundice, bilirubinuria, fatigue, nausea, vomiting, right upper quadrant pain, ascites, unexplained oedema, easy bruisability)	• Immediately perform a comprehensive hepatic workup. • If liver injury is confirmed, the drug should be discontinued.

להלן העדכון העיקרי בעלון לצרכן:

לפני השימוש בתרופה

...

אזהרות מיוחדות הנוגעות לשימוש בתרופה

יש להיוועץ ברופא לפני התחלת הטיפול בסומאברט™.

- ...
- הרופא יערוך בדיקות של תפקודי כבד לפני ובמהלך הטיפול עם סומאברט, אם תוצאות הבדיקות אינן תקינות, הרופא יידע אותך על אפשרויות הטיפול. עם התחלת הטיפול,הרופא או האחות יבצעו מעקב אחר רמות אנזימי הכבד שבדמך כל 4-6 שבועות בחצי שנה הראשונה לטיפול בסומאברט™. יש להפסיק את הטיפול בסומאברט™ אם סימני מחלת הכבד נמשכים.
- יש לערוך מעקב תפקודי כבד פעם ברבעון במשך 6 חודשים הבאים ולאחר מכן מעקב דו שנתי בשנה שאחריה.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע שאינם מהווים החמרה.
העלונים לרופא ולצרכן נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, רח' שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה
גילי קבשה
רוקחת ממונה