יולי 2023

רוקח/ת נכבד/ה,רופא/ה נכבד/ה,

חברת פרופארם בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

TERLIPRESSIN ALTAN 1 MG

טרליפרסין אלטן 1 מ"ג

חומר פעיל: TERLIPRESSIN (AS ACETATE) 0.1MG/ML

צורת מינון: SOLUTION FOR INJECTION

צורת המתן:.I.V

עדכונים בעלון לרופא

<u>התויה כפי שאושרה בתעודת הרישום:</u>

Bleeding oesophageal varices. Treatment of type I hepatorenal syndrome

<u>ברצוננו להודיע שהעלונים עודכנו, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות /שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):</u>

עדכונים עיקריים בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ampoule of 8.5 ml solution contains 1 mg terlipressin acetate.
Each ml contains 0.12 mg terlipressin acetate, corresponding to 0.1 mg terlipressin.
[…]

4.4 Special warnings and precautions for use

Type 1 hepatorenal syndrome
Prior to use of terlipressin for hepatorenal syndrome, it must be ascertained that the patient has an acute functional renal failure and this functional renal failure does not respond to a suitable plasma expansion therapy.

Renal impairment
Terlipressin should be avoided in patients with advanced renal dysfunction, i.e., baseline serum creatinine 442 µmol/L (5.0 mg/dL), when treated with terlipressin for type 1 hepatorenal syndrome, unless the benefit is judged to outweigh the risks. Reduced efficacy in reversal of hepatorenal syndrome, increased risk of adverse events, and increased mortality in this patient group have been observed in clinical trials.

Hepatic impairment
Terlipressin should be avoided in patients with severe liver disease defined as Acute-on-Chronic Liver Failure (ACLF) grade 3 and/or a Model for End-stage Liver Disease (MELD) score≥39, when treated with terlipressin for type 1 hepatorenal syndrome, unless the benefit is judged to outweigh the risks. Reduced efficacy in reversal of hepatorenal syndrome, increased risk of respiratory failure, and increased mortality in this patient group have been observed in clinical trials.

Respiratory events
Fatal cases of respiratory failure, including respiratory failure due to fluid overload, have been reported in patients treated with terlipressin for type 1 hepatorenal syndrome.
Patients with a new onset of breathing difficulties or worsening of respiratory disease should be

stabilised prior to receiving their first dose of terlipressin.

Caution should be exercised when terlipressin is administered together with human albumin as part of the standard of care for type 1 hepatorenal syndrome. In case of signs or symptoms of respiratory failure or fluid overload, dose reduction of human albumin should be considered. If respiratory symptoms are severe or do not resolve, treatment with terlipressin should be discontinued.

Sepsis/ septic shock
Cases of sepsis/septic shock, including fatal cases, have been reported in patients treated with terlipressin for type 1 hepatorenal syndrome. Patients should be monitored daily for any signs or symptoms suggestive of infection.

~~Cardiac, pulmonary and vascular disease~~Monitoring during treatment
During treatment regular monitoring and control of blood pressure, ECG or heart rate, oxygen saturation, serum levels of sodium and potassium, as well as fluid balance are required. Particular care is required in management of cardiovascular or pulmonary disease since terlipressin may induce ischemia and pulmonary vascular congestion.
[…]

4.8 Undesirable effects
The most frequently ~~commonly~~ reported undesired effects in clinical trials are paleness, increased blood pressure, abdominal pain, nausea, diarrhoea, and headache.
Tabulated list of adverse reactions
There are adverse reactions that appear twice in the table, as the estimated frequencies differ between indications.
Very common (<1/10)
Respiratory,thoracic and mediastinal disorders:
Respiratory failure[a]
Dyspnoea[a]
[…]
Common (≥1/100 to <1/10)
SOC Infections and infestations:
Sepsis/septic shock
Respiratory, thoracic and mediastinal disorders:
Respiratory distress[a]
Pulmonary oedema[a]
[…]

5.2 Pharmacokinetic properties
Terlipressin Altan 1 mg is administered by bolus IV injection. It shows a biphasic plasma level curve which indicates that a two compartment model can be applied. The half-life of distribution (T ½ α) is about 8-10 minutes. The half-life of elimination (T ½ β) is about 50-70 minutes.

העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.
ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת פרופארם בע"מ, טל 04-6294242.

בברכה,

מירי חזן
רוקחת ממונה