מרץ 2023

רופא/ה, רוקח/ת נכבד/ה,

אנו רוצים להביא לידיעתך כי עלון לרופא של תכשיר Glypressin עודכן בהתאם לחוזר המחלקה לרישום תכשירים בנושא "מסלול הודעה (נוטיפיקציה) לעדכון עלונים של תכשירים הומניים ווטרינריים – עדכון ינואר 2023".

שם תכשיר:

Glypressin

חומר פעיל:

Each vial with powder contains terlipressin acetate 1 mg.

התוויה:

Bleeding oesophageal varices.

Treatment of type I hepatorenal syndrome.

מצורף עלון מעודכן. החלקים שעודכנו מסומנים. עדכונים עיקריים המהווים **החמרות** מפורטים בטבלה מטה. חשוב להדגיש שהטבלה אינה מכילה את כל העדכונים. לכל העדכונים יש לעיין בעלון המצורף.

בעלון לרופא	
העדכון (למידע מלא בפרק זה יש לעיין בעלון לרופא)	פרק
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 ≥ 442µmol/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.	**4.4 Special warnings and precautions for use**

Patients with a new onset of breathing difficulties or worsening of respiratory disease should be stabilized 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. 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. Caution should be exercised in treating patients with hypertension, recognised heart disease, renal dysfunction, cerebral or peripheral vascular disease, asthma or respiratory failure.	
Respiratory, thoracic and mediastinal disorders: Very common (<1/10)): Respiratory failure[b] Dyspnea[b] Common (≥1/100 to <1/10): Respiratory distress[b] Pulmonary oedema[b] [b] *Applicable to other approved indications apart from type 1 hepatorenal syndrome.*	**4.8 Undesirable effects**

העלון המעודכן נשלח לפרסום באתר האינטרנט של אגף הרוקחות.

ניתן גם לקבל את העלון בעותק קשיח ע"י פניה לבעל הרישום: חברת פרינג פרמצאוטיקלס בע"מ,

רחוב השיטה 8 קיסריה.

בברכה,
אורית זוזוט

מנהלת רגולציה ואיכות
פרינג פרמצאוטיקלס בע"מ