

יולי 2020

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 ווטרinariים – עדכון דצמבר 2019".

שם תכשיר:

Glypressin

חומר פעיל:

Each ampoule 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	
פרק	העדכון (למידע מלא בפרק זה יש לעיין בעלון לרופא)
4.4 Special warnings and precautions for use	<p><u>Cardiac, pulmonary and vascular disease</u></p> <p><u>During treatment regular monitoring and control of blood pressure, ECG, heart rate, serum levels of sodium and potassium, as well as fluid balance are required.</u></p> <p><u>Blood pressure, heart rate and fluid balance should be monitored during treatment.</u></p>

Caution should be exercised in treating patients with hypertension, recognised heart disease, renal dysfunction, cerebral or peripheral vascular disease, asthma or respiratory failure.

Injection site reaction

To avoid local necrosis at the injection site, the injection must be administered intravenously.

Septic shock

In patients with septic shock with a low cardiac output terlipressin should not be used.

Torsade de pointes

During clinical trials and post-marketing experience, several cases of QT interval prolongation and ventricular arrhythmias including "Torsade de pointes" have been reported (see section 4.8). In most cases, patients had predisposing factors such as basal prolongation of the QT interval, electrolyte abnormalities (hypokalemia, hypomagnesemia) or medications with concomitant effect on QT prolongation. Therefore, extreme caution should be exercised in the use of terlipressin in patients with a history of QT interval prolongation, electrolyte abnormalities, or concomitant medications that can prolong the QT interval (see section 4.5).

The hypotensive effect of non-selective beta-blockers on the portal vein is increased with terlipressin. Concomitant treatment with medicinal products with a known bradycardiac effect (e.g. propofol, sufentanil) may lower the heart rate and cardiac output. These effects are due to reflexogenic inhibition of the cardiac activity via the vagus nerve due to the elevated blood pressure. Terlipressin can trigger "torsade de pointes" (see sections 4.4 and 4.8). Therefore, extreme caution should

4.5 Interaction with other medicinal products and other forms of interaction

FERRING

PHARMACEUTICALS

be exercised in the use of terlipressin in patients with concomitant medications that can prolong the QT interval, such as class IA and III antiarrhythmics, erythromycin, certain antihistamines and tricyclic antidepressants or medications that may cause hypokalaemia or hypomagnesaemia (e.g. some diuretics).

Respiratory, thoracic and mediastinal disorders: Uncommon ($\geq 1/1,000$ to $< 1/100$):
Respiratory distress
Pulmonary oedema
Respiratory failure

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

34/05/2020

2020

1. The first part of the document is a list of the names of the members of the committee who have been appointed to the various sub-committees. The names are listed in alphabetical order of their surnames.

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