יולי 2026

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 שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות /שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):</u>

4.4 Special warnings and precautions for use

[…]

Skin necrosis

During post-marketing experience with terlipressin several cases of cutaneous ischaemia and necrosis unrelated to the injection site have been reported (see section 4.8). Patients with diabetes mellitus and/or obesity seem to have a greater tendency to this reaction. Therefore, caution should be exercised when administering terlipressin in these patients.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported undesired effects in clinical trials are abdominal pain, nausea, diarrhoea, pallor, dyspnoea (for type 1 HRS), respiratory failure (for type 1 HRS), vomiting and bradycardia.

The antidiuretic effect of terlipressin may cause hyponatraemia unless the fluid balance is controlled. ~~paleness, increased blood pressure, and headache.~~

MedDRA System Organ Class	**Very common (<1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to < 1/100)**	~~**Rare (≥ 1/10,000 to < 1/1,000**~~ **Frequency not known*****
Metabolism and nutrition disorders		Hyponatraemia	~~Hyponatraemia~~	
Nervous system disorders		Headache		
Cardiac disorders		Chest pain Bradycardia Tachycardia	Atrial fibrillation Ventricular extracystoles* ~~Tachycardia~~ Myocardial infarction Torsade de pointes Cardiac failure	

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Vascular disorders		Vasoconstriction Peripheral ischemia Pallor Hypertension Cyanosis	~~Hot flush~~	
Respiratory, thoracic and mediastinal disorders	Respiratory failure[a] Dyspnoea[a]	Respiratory distress[a] Pulmonary oedema[a] Dyspnoea[b]	Respiratory distress[b] ~~Pulmonary oedema[b]~~ Respiratory failure[b]	~~Dyspnoea[b]~~
Gastrointestinal disorders	Abdominal pain	~~Abdominal pain~~ Nausea Vomiting Diarrhoea	~~Nausea~~ Intestinal ischemia ~~Vomiting~~	
Skin and subcutaneous tissue disorders			Skin necrosis (unrelated to the site of administration)*, **	
Pregnancy, puerperium and perinatal conditions			~~Uterine hypertonus~~ ~~Uterine ischemia~~	Uterine hypertonus
Reproductive system and breast disorders				Uterine ischemia
General disorders and administration			Injection site necrosis ~~Chest pain~~	

[a] Applicable to type 1 hepatorenal syndrome. Frequencies are calculated based on the pooled safety population in the OT-0401, REVERSE and CONFIRM clinical trials.
[b] Applicable to other approved indications apart from type 1 hepatorenal syndrome.
* Adverse reactions identified from post-marketing sources are presented by frequency category based on a theoretically calculated frequency if not observed in clinical trials.
** See section 4.4 for further information.
*** Frequencies of these adverse events cannot be estimated from the available data.

העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.
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בברכה,

חברת פרופארם בע"מ