Safety Alert **March 2024**

Terlipressin– Avoidance in patients with advanced renal dysfunction& Risk of Respiratory failure and dyspnoea

EDA performs label update to include the following:

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Use in renal impairment

Prior to treatment of Type 1 HRS, other types of acute kidney injury should be ruled out.
As data are limited terlipressin should be used with caution and under strict monitoring of the patients in renal impairment.Terlipressin should be avoided in patients with advanced renal dysfunction, i.e., baseline serum creatinine ≥ 442 micromoles/L (5.0 mg/dL), when treated with terlipressin for Type 1 HRS, unless the benefit is judged to outweigh the risks. Reduced efficacy in reversal of HRS, increased risk of adverse events, and increased mortality in this patient group have been observed in clinical trials.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

There are adverse reactions that appear twice in the table, as the estimated frequencies differ between indictions

MedDRA System Organ Class Disorder	*GASTROINTESTI NAL*
RESPIRATORY	*Respiratory failure Dyspnoea*
GASTROINTESTI NAL	*Abdominal pain*

Background:

Terlipressin is indicated for the:

• treatment of bleeding oesophageal varices (BOV);
• treatment of patients with Type 1 hepatorenal syndrome (HRS) who are actively being considered for liver transplant.

References:

TGA *(Click here)*