Actor Portrayal

Terlivaz®
terlipressin for injection

For your patients with alcoholic hepatitis

If Hepatorenal Syndrome (HRS) with rapid reduction in kidney function is confirmed,

REVERSING IT MAY BE POSSIBLE

INDICATION AND LIMITATION OF USE

TERLIVAZ® is indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.

- Patients with a serum creatinine >5 mg/dL are unlikely to experience benefit.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS OR FATAL RESPIRATORY FAILURE

- **TERLIVAZ may cause serious or fatal respiratory failure. Patients with volume overload or with acute-on-chronic liver failure (ACLF) Grade 3 are at increased risk. Assess oxygenation saturation (e.g., SpO_2) before initiating TERLIVAZ.**
- **Do not initiate TERLIVAZ in patients experiencing hypoxia (e.g., SpO_2 <90%) until oxygenation levels improve. Monitor patients for hypoxia using continuous pulse oximetry during treatment and discontinue TERLIVAZ if SpO_2 decreases below 90%.**

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

WALT, 40

Terlivaz®
terlipressin for injection

SYMPTOMS

Presents with severe abdominal swelling, shortness of breath, fever, and fatigue

SOCIAL HISTORY

History of chronic, heavy alcohol use; recently entered into an abstinence program

This hypothetical patient is provided for general medical education purposes only and is not intended as medical practice guidance. You are advised to exercise your own medical judgment when making individual patient treatment decisions.

COMORBIDITIES

- Severe alcoholic hepatitis and cirrhosis
- Ascites
- Hypertension
- History of variceal bleeding
- Not currently eligible for a liver transplant[a]

CONCOMITANT MEDICATIONS

- Spironolactone
- Furosemide
- Pentoxifylline
- Carvedilol

KEY CLINICAL ASSESSMENT AND LAB RESULTS

ACLF[b]	Grade 2
MELD[c]	28
Total Bilirubin	13.3 mg/dL
SCr	***Day 1:*** 2.1 mg/dL ***Day 3:*** 2.3 mg/dL
HE	Grade 1
INR	1.5
MAP	75 mmHg
SpO_2	98% on room air

Historical baseline SCr (value obtained within the last 2 weeks): 1.0 mg/dL

ACLF, acute-on-chronic liver failure; HE, hepatic encephalopathy; INR, international normalized ratio; MAP, mean arterial pressure; MELD, model for end-stage liver disease; SCr, serum creatinine; SpO_2, oxygen saturation.

[a]TERLIVAZ-related adverse reactions (respiratory failure, ischemia) may make a patient ineligible for liver transplantation, if listed. For patients with high prioritization for liver transplantation (e.g., MELD ≥35), the benefits of TERLIVAZ may not outweigh its risks.[1]
[b]Calculated based on the Chronic Liver Failure–Sequential Organ Failure Assessment (CLIF-SOFA) scoring system.[2]
[c]Calculated based on the INR, and serum bilirubin and creatinine levels.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

TERLIVAZ is contraindicated:
- In patients experiencing hypoxia or worsening respiratory symptoms.
- In patients with ongoing coronary, peripheral, or mesenteric ischemia.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Confirm if TERLIVAZ®, the first and only FDA-approved treatment for adult HRS patients with rapid reduction in kidney function, is appropriate[1]

Terlivaz® terlipressin for injection

Using the 2021 AASLD diagnostic algorithm, Walt was diagnosed with HRS-AKI based on[3]:

- Presence of cirrhosis with ascites
- An acute rise in SCr[a] from a baseline of 1.0 mg/dL to 2.1 mg/dL after day 1 of hospital admission indicates the presence of AKI
- Clinical assessments, including urine findings, that rule out other causes of kidney dysfunction such as ATN, AIN, UTI, and UTO
- No improvement in SCr level following 2-day diuretic withdrawal and albumin challenge. His SCr increased from 2.1 mg/dL to 2.3 mg/dL (day 3 of hospital admission)
- Absence of shock
- No recent or current use of nephrotoxic medications (NSAIDs, aminoglycosides, or iodinated contrast media)
- No signs of structural kidney injury, as indicated by proteinuria (>500 mg per day), microhematuria (>50 red blood cells per high-power field), and/or abnormal renal ultrasonography

BASED ON AASLD GUIDANCE FOR TREATING HRS-AKI, TERLIPRESSIN IS RECOMMENDED[3]

Walt's HCP thought he was an appropriate patient for TERLIVAZ treatment because he had[1]:

- ✓ No signs of hypoxia or worsening respiratory symptoms[b]
- ✓ No coronary, peripheral, or mesenteric ischemia
- ✓ No signs of intravascular volume overload[c]
- ✓ ACLF Grade <3
- ✓ SCr ≤5 mg/dL[d]

AASLD, American Association for the Study of Liver Diseases; AIN, acute interstitial nephritis; AKI, acute kidney injury; ATN, acute tubular necrosis; HRS-AKI, hepatorenal syndrome–acute kidney injury; NSAID, nonsteroidal anti-inflammatory drug; UTI, urinary tract infection; UTO, urinary tract obstruction.

[a]Defined as an increase ≥0.3 mg/dL from baseline within 48 hours or ≥50% increase known or presumed to have occurred within the preceding 7 days. By convention, stable creatinine values within the previous 3 months before hospitalization can be used as the baseline in the diagnosis of AKI.[3]

[b]Do not initiate TERLIVAZ in patients experiencing hypoxia (e.g., SpO_2 <90%) until oxygenation levels improve.[1]

[c]Manage intravascular volume overload by reducing or discontinuing the administration of albumin and/or other fluids and through judicious use of diuretics. Temporarily interrupt, reduce, or discontinue TERLIVAZ treatment until patient volume status improves.[1]

[d]Patients with SCr >5 mg/dL are unlikely to experience benefit.[1]

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Serious or Fatal Respiratory Failure:** Obtain baseline oxygen saturation and do not initiate TERLIVAZ in hypoxic patients. Monitor patients for changes in respiratory status using continuous pulse oximetry and regular clinical assessments. Discontinue TERLIVAZ in patients experiencing hypoxia or increased respiratory symptoms.

  Manage intravascular volume overload by reducing or discontinuing the administration of albumin and/or other fluids and through judicious use of diuretics. Temporarily interrupt, reduce, or discontinue TERLIVAZ treatment until patient volume status improves. Avoid use in patients with ACLF Grade 3 because they are at significant risk for respiratory failure.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Earlier diagnosis and treatment may lead to better outcomes.[4,5]

REVIEW AASLD GUIDANCE[3] AT TERLIVAZ.COM TO IDENTIFY HRS-AKI PATIENTS AND TREATMENT RECOMMENDATIONS.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

- **Ineligibility for Liver Transplant:** TERLIVAZ-related adverse reactions (respiratory failure, ischemia) may make a patient ineligible for liver transplantation, if listed. For patients with high prioritization for liver transplantation (e.g., MELD ≥35), the benefits of TERLIVAZ may not outweigh its risks.
- **Ischemic Events:** TERLIVAZ may cause cardiac, cerebrovascular, peripheral, or mesenteric ischemia. Avoid use of TERLIVAZ in patients with a history of severe cardiovascular conditions or cerebrovascular or ischemic disease. Discontinue TERLIVAZ in patients who experience signs or symptoms suggestive of ischemic adverse reactions.
- **Embryo-Fetal Toxicity:** TERLIVAZ may cause fetal harm when administered to a pregnant woman. If TERLIVAZ is used during pregnancy, the patient should be informed of the potential risk to the fetus.

Adverse Reactions

- The most common adverse reactions (≥10%) include abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

References:

1. TERLIVAZ® (terlipressin). Prescribing Information. Bridgewater, NJ: Mallinckrodt Hospital Products Inc; 2023.
2. Moreau R, Jalan R, Gines P, et al. Acute-on-chronic liver failure is a distinct syndrome that develops in patients with acute decompensation of cirrhosis. *Gastroenterology*. 2013;144(7):1426-1437.e14379.
3. Biggins SW, Angeli P, Garcia-Tsao G, et al. Diagnosis, evaluation, and management of ascites, spontaneous bacterial peritonitis and hepatorenal syndrome: 2021 practice guidance by the American Association for the Study of Liver Diseases. *Hepatology*. 2021;74:1014-1048.
4. Angeli P, Gines P, Wong F, et al. Diagnosis and management of acute kidney injury in patients with cirrhosis: revised consensus recommendations of the International Club of Ascites. *Gut*. 2015;64(4):531-537. doi:10.1136/gutjnl-2014-308874
5. Curry MP, Vargas HE, Befeler AS, Pyrsopoulos NT, Patwardhan VR, Jamil K. Early treatment with terlipressin in patients with hepatorenal syndrome yields improved clinical outcomes in North American studies. *Hepatol Commun*. 2023;7(1):e1307. doi:10.1097/01.HC9.0000897228.91307.0c

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