

Defitelio® (defibrotide sodium)



When requesting Defitelio® (defibrotide sodium), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication

Defitelio® (defibrotide sodium) is indicated for the treatment of individuals with hepatic veno-occlusive disease, also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation.¹

Approved Off-label Compendial uses²

- No off-label uses meet evidence standards

Coverage Guidelines¹

For the approved indication, the individual does **not** have the following contraindication or exclusion to therapy:

- Concomitant administration with systemic anticoagulant or fibrinolytic therapy
- Active bleeding

Hepatic Veno-Occlusive Disease

The individual must meet **all** of the following criteria for approval:

- Diagnosis of hepatic veno-occlusive disease
- Renal and/or pulmonary dysfunction following hematopoietic stem-cell transplantation

Approval duration: 60 days

Additional Information for Prescribers¹

- Defitelio® (defibrotide sodium) may increase the risk of bleeding in patients with hepatic veno-occlusive disease after hematopoietic stem-cell transplantation. Monitor individuals for bleeding. Withhold or discontinue Defitelio® (defibrotide sodium) if significant bleeding occurs.
- If severe or life threatening allergic reaction occurs, discontinue Defitelio® (defibrotide sodium), treat according to standard of care, and monitor until signs and symptoms resolve.

References

1. Defitelio (defibrotide sodium) prescribing information. Palo Alto, CA: Jazz Pharmaceuticals Merck and Company, Inc: Revised March 2016. <https://defitelio.com/DefitelioPI.pdf>. Accessed January 30, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed January 30, 2017. <https://www.micromedexsolutions.com>.