

YONDELIS® (trabectedin) YONDELIS – Capillary Leak Syndrome

SUMMARY

- Capillary leak syndrome (CLS) characterized by hypotension, edema, and hypoalbuminemia has been reported with YONDELIS, including serious CLS resulting in death. Monitor for signs and symptoms of CLS. Discontinue YONDELIS and promptly initiate standard management for patients with CLS, which may include a need for intensive care.¹
- Because cases of capillary leak syndrome were identified during post-approval use of YONDELIS and were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.¹
- Patients should be advised to report symptoms of CLS such as edema with or without hypotension.¹
- Please refer to the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, PATIENT COUNSELING INFORMATION, and PATIENT INFORMATION sections of the full Prescribing Information.

POSTMARKETING EXPERIENCE

During clinical trials with YONDELIS, the frequency of capillary leak syndrome was uncommon ($\geq 0.1\%$ and $< 1\%$).²

Cases of capillary leak syndrome were also reported spontaneously during post-approval use of YONDELIS. Because these cases were identified during post-approval use and were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.^{1,2}

OTHER RELEVANT LITERATURE

Case reports describing potential cases of CLS in patients treated with YONDELIS have been published.^{3,4} One report described findings consistent with pulmonary edema related to generalized capillary leak syndrome.⁴ Unilateral pulmonary edema was also reported in a second case.³

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 10 October 2024.

REFERENCES

1. YONDELIS (trabectedin) [Prescribing Information]. Horsham, PA: Janssen Products, LP; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/YONDELIS-pi.pdf>.
2. Data on File. Trabectedin Company Core Data Sheet. Janssen Research & Development, LLC; 2016.
3. Tirumani SH, Jagannathan JP, O'Regan K, et al. Molecular targeted therapies in non-GIST soft tissue sarcomas: what the radiologist needs to know. *Cancer Imaging*. 2013;13(2):197-211.
4. Shah SH, Jagannathan JP, Krajewski K, et al. Uterine sarcomas: then and now. *AJR Am J Roentgenol*. 2012;199(1):213-223.