

## **YONDELIS® (trabectedin)**

### **YONDELIS – Stability of Reconstituted and Diluted Solution**

#### **SUMMARY**

- YONDELIS is available as 1 mg, lyophilized powder in a single-dose vial for reconstitution. The powder must be reconstituted with Sterile Water for Injection, USP (WFI) and then further diluted with 0.9% Sodium Chloride (NSS), USP or 5% Dextrose Injection, USP (D5W).<sup>1</sup>
- Infuse the reconstituted, diluted solution over 24 hours through a central line using an infusion set with a 0.2 micron polyethersulfone (PES) in-line filter to reduce the risk of exposure to adventitious pathogens that may be introduced during solution preparation.<sup>1</sup>
- Complete infusion within 30 hours of initial reconstitution. Discard any unused portion of the reconstituted product or of the infusion solution.<sup>1</sup>
- Studies evaluating physical and chemical stability of reconstituted (to 50 µg/mL with WFI) and diluted (with NSS or D5W) drug product were conducted for up to 30 hours at either room temperature with ambient light or under refrigeration. Product was found to be stable. Studies beyond 30 hours were not conducted.<sup>2</sup>
- In summary, the performed studies confirm the compatibility of YONDELIS with NSS and D5W diluents, and with infusion containers constructed with polyvinylchloride, glass, or polyethylene.<sup>2</sup>
- Please refer to the DOSAGE AND ADMINISTRATION section of the full Prescribing Information.

#### **STABILITY AFTER RECONSTITUTION**

Janssen Products, LP cannot recommend any practices, procedures, usage, or storage conditions that deviate from product labeling and are not approved by the Food and Drug Administration. The information below is provided in response to your unsolicited request.

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#### **LITERATURE SEARCH**

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 03 August 2023.

#### **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. New Drug Application Module 3.2.P.2.6 Compatibility. Janssen Research & Development, LLC. 2015.