

YONDELIS® (trabectedin) YONDELIS – Stability of Unopened Vials

SUMMARY

- YONDELIS is supplied in a single-dose glass vial containing 1 mg trabectedin. Store YONDELIS vials in a refrigerator at 2°C to 8°C (36°F to 46°F).¹
- Excursions from -20°C to 2°C (-4°F to 36°F) are allowed for a maximum period of 21 days.²
- Excursions from 8°C to 25°C (46°F to 77°F) are allowed for a maximum period of 21 days.²

STABILITY AND TEMPERATURE EXCURSION DATA

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. Stability data not included in the product label are available for situations outside of recommended storage requirements. This information is provided in response to your unsolicited request. These data were collected in strictly controlled environments. It is not possible to predict and design studies that reflect every combination or duration of temperatures that a customer's product may encounter. Therefore, caution is recommended in assessing the effects of specific excursions on a product.

Stability studies were conducted with YONDELIS vials to provide the acceptable limits for temperature excursions outside of the recommended storage conditions of 2°C to 8°C (36°F to 46°F).² Results are shown in the [table](#) below.

Temperature Excursions²

Excursion Temperature Range	Acceptable Limit
-20°C to 2°C (-4°F to 36°F)	21 days
8°C to 25°C (46°F to 77°F)	21 days

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. Technical Document Proven Temperature Ranges for JSC Drug Products. TV-TEC-102593. 2023.