

YONDELIS® (trabectedin) YONDELIS - Administration Sets

SUMMARY

- YONDELIS diluted solution is compatible with Type 1 colorless glass vials, polyvinylchloride (PVC) and polyethylene (PE) bags and tubing, PE and polypropylene (PP) mixture bags, polyethersulfone (PES) in-line filters, titanium, platinum or plastic ports, silicone and polyurethane catheters, and pumps having contact surfaces made of PVC, PE, or PE/PP.¹
- Infuse the reconstituted, diluted solution over 24 hours through a central venous line using an infusion set with a 0.2 micron PES in-line filter to reduce the risk of exposure to adventitious pathogens that may be introduced during solution preparation.¹
- Please refer to the DOSAGE AND ADMINISTRATION section of the full Prescribing Information.

ADMINISTRATION SETS

PLEASE NOTE: Janssen Products, LP does not endorse the use of a specific manufacturer of administration sets to be used in conjunction with YONDELIS. Health care professionals should confirm that the specific administration set used with YONDELIS meets the requirements per the YONDELIS Prescribing Information.

- Due to the physicochemical characteristics of the trabectedin molecule, the reconstituted, diluted YONDELIS solution is not compatible with all in-line filter intravenous administration sets.² In addition, the use of an add-on filter is not recommended. Extensive studies have been conducted to demonstrate compatibility with the materials listed in the YONDELIS Prescribing Information, and the data and methodology were reviewed by the FDA during the approval process.²
- YONDELIS can be administered by either an ambulatory pump or a stationary pump. An example of a compatible administration set for an ambulatory pump is the CADD® filtered Administration Set (current part number 21-7394-24).^{3, 4, 5} An example of a compatible administration set for a stationary pump is the B. Braun Vista® filtered administration set (current product code V9902F) for use in conjunction with the Vista Basic® infusion pump.⁶ However, other administration sets for use with either ambulatory or stationary pumps from additional manufacturers may also be appropriate to use when composed of the approved materials.
- Contact your supplier or manufacturer directly to obtain appropriate administration sets.

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 14 July 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.
3. CADD® Administration Set (current part number 21-7394-24). Smiths Medical; 2018.
4. CADD® Administration Sets [customer communication]. Smiths Medical; October 2017.
5. Data on File. Correspondence from Janssen Research & Development, LLC. (Email dated November 11, 2015). Janssen Research & Development, LLC. 2015.
6. B. Braun Infusion Systems Product Catalog (current product code V9902F). B. Braun Medical Inc.; January 2022.