

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

YONDELIS

trabectedin

Consumer Medicine Information

This leaflet provides important information about using YONDELIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using YONDELIS.**

Where to find information in this leaflet:

1. Why am I using YONDELIS?
2. What should I know before I use YONDELIS?
3. What if I am taking other medicines?
4. How is YONDELIS given?
5. What should I know while using YONDELIS?
6. Are there any side effects?
7. Product details

1. Why am I using YONDELIS?

YONDELIS contains the active ingredient trabectedin. YONDELIS is an anti-cancer medicine that works by preventing the tumour cells from multiplying.

YONDELIS is used for the treatment of patients with liposarcoma or leiomyosarcoma, which are types of soft tissue sarcoma, when previous medicines have been unsuccessful, or the patients are unsuited to receive them. Soft tissue sarcoma is a malignant disease that starts somewhere in the soft tissues, such as the muscles, fat or other tissues (for example cartilages or vessels).

2. What should I know before I use YONDELIS?

Warnings

Do not use YONDELIS if:

- you are allergic to trabectedin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver, kidney or heart problems
- you have any serious infections
- you are pregnant or plan to become pregnant
- you are breast-feeding
- you will receive yellow fever vaccine
- you are a child or adolescent

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have liver or kidney problems
- cardiac problems or a history of cardiac problems
- left ventricular ejection fraction (LVEF) under the lower limit of normal
- received high anthracycline dose treatment in the past

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional

information under Section 6. **Are there any side effects?**

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. YONDELIS must not be used during pregnancy.

Tell your doctor immediately if you become pregnant. Genetic counselling is recommended since YONDELIS can cause genetic damage.

Adequate contraceptive precautions must be used by:

- women of childbearing potential when receiving YONDELIS and for 3 months following the end of treatment.
- men in fertile age when receiving YONDELIS and for 5 months following the end of treatment.

Tell your doctor if you are planning to have children.

Patients should seek advice on ovules or sperm conservation prior to treatment because of the risk of irreversible infertility due to therapy with YONDELIS. Genetic counselling is also recommended for patients wishing to have children after therapy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

YONDELIS must not be given to patients who are breast-feeding. Therefore you must stop breast-feeding before you start your treatment and you must not begin breast-feeding again until your doctor has confirmed that it is safe to do so.

YONDELIS contains potassium

This medicine contains potassium, less than 1 mmol (39 mg) per vial, and can therefore be considered as essentially “potassium-free”