

PATIENT INFORMATION
YONDELIS® (yon-DEL-ess)
(trabectedin)
for injection

What is YONDELIS?

YONDELIS is a prescription medicine used to treat people with liposarcoma or leiomyosarcoma that:

- cannot be treated with surgery or has spread to other areas of the body, **and**
- who have received treatment with certain other medicines.

It is not known if YONDELIS is safe and effective in children.

Who should not receive YONDELIS?

You will not be given YONDELIS if you have had a severe allergic reaction to trabectedin, the active ingredient in YONDELIS. See the end of this leaflet for a complete list of ingredients in YONDELIS.

What should I tell my healthcare provider before receiving YONDELIS?

Before receiving YONDELIS, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- are pregnant or plan to become pregnant. YONDELIS can harm your unborn baby. You should not become pregnant during treatment with YONDELIS.
 - **Females** who are able to become pregnant should use an effective form of birth control during treatment with YONDELIS and for 2 months after your last dose of YONDELIS.
 - **Males** should use an effective form of birth control when having sex with female partners who are able to become pregnant, during your treatment with YONDELIS and for 5 months after your last dose of YONDELIS.
- are breastfeeding or plan to breastfeed. It is not known if YONDELIS passes into your breast milk. You should not breastfeed during treatment with YONDELIS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive YONDELIS?

- YONDELIS is given by an intravenous (IV) infusion into a vein over 24 hours. To help avoid irritation at the site where it is infused, YONDELIS is given to you into a large vein through a type of IV line called a central venous line.
- YONDELIS is usually given every 3 weeks.
- Your healthcare provider may decrease your dose or delay doses if you have certain side effects. If you have any side effects that are severe, your healthcare provider may stop your treatment with YONDELIS.
- Before each treatment with YONDELIS, you will receive a steroid medicine to help reduce your risk of getting certain side effects.
- Your healthcare provider will decide how long you will continue treatment with YONDELIS.
- Your healthcare provider may do certain tests while you are receiving YONDELIS to check you for side effects, and to see how well you respond to the treatment.

What should I avoid while receiving YONDELIS?

- Avoid grapefruit and grapefruit juice during treatment with YONDELIS.

What are the possible side effects of YONDELIS?

YONDELIS may cause serious side effects, including:

- **Severe infections due to decreased white blood cells. Decreased low white blood cell count is common with YONDELIS, but it can also lead to severe infections and death.** Your healthcare provider may need to decrease your dose of YONDELIS, delay or stop your treatment, if your white blood cell count is too low or you get a serious infection. Call your healthcare provider right away if you develop fever or other signs of infection.
- **Severe muscle problems (rhabdomyolysis).** YONDELIS can cause muscle problems that can be severe and lead to death. Tell your healthcare provider right away if you have severe muscle pain or weakness.
- **Liver problems, including liver failure.** Tell your healthcare provider right away if you get:
 - yellowing of your skin and whites of your eyes
 - pain in your upper right stomach-area (abdomen)
 - nausea
 - vomiting
 - generally do not feel well
 - problem with concentration
 - confusion
 - sleepiness
- **Heart muscle problems, including heart failure.** Your healthcare provider will do a test to check your heart function before you start YONDELIS, and during treatment. If you develop heart muscle problems or heart failure during treatment with YONDELIS, your doctor may stop your treatment. Tell your healthcare provider right away if you develop new chest pain, shortness of breath, tiredness, swelling of your legs, ankles, or feet, or heart palpitations.
- **Leakage of YONDELIS out of your vein during the infusion.** If YONDELIS leaks into the tissues around your infusion site, it can cause damage and death of tissue cells around the infusion site. You may need to have surgery to remove any dead tissue. Tell your healthcare provider right away if you see any YONDELIS leaking out of your vein or around the catheter during your infusion, or if you notice any redness, swelling, itching or discomfort at the infusion site at any time.
- Some people have had allergic reactions to YONDELIS. Some of these reactions were severe. Your healthcare provider may need to stop your treatment with YONDELIS, and may give you medicines to treat the allergic reaction. **Signs of an allergic reaction** can include: difficulty breathing, chest tightness, wheezing, swelling of the lips, or skin rash.

The most common side effects of YONDELIS include:

- nausea
- tiredness
- vomiting
- constipation
- decreased appetite
- diarrhea
- swelling of your hands, ankles, or feet
- shortness of breath
- headache
- decreased red cell count (cells which carry oxygen in the blood). Tell your healthcare provider if you feel more tired than usual or look pale.
- decreased platelet cell counts (cells which help blood to clot). Tell your healthcare provider if you bruise easily or have bleeding.
- changes in liver and kidney function blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of YONDELIS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of YONDELIS

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about YONDELIS that is written for health professionals.

What are the ingredients in YONDELIS?

Active ingredient: trabectedin

Inactive ingredients: potassium dihydrogen phosphate, sucrose, phosphoric acid and potassium hydroxide.

Manufactured by: Baxter Oncology GmbH, Halle/Westfalen Germany

Manufactured for: Janssen Products, LP, Horsham, PA

For more information, call 1-800-526-7736 or go to www.YONDELIS.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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