

UNDERSTANDING
YOUR
TREATMENT



To learn more about an infusion with YONDELIS[®], [click here](#) to watch the YONDELIS[®] infusion video

Please read Important Safety Information on the following pages and [click here](#) to read the full Prescribing Information for YONDELIS[®].

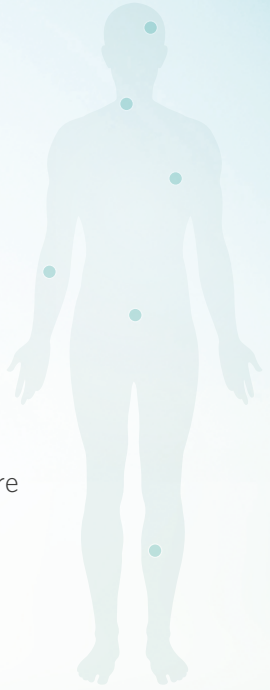
INTRODUCTION

This brochure will help answer your questions about your disease and treatment.

This booklet is not intended to replace any guidance or advice from your physician. You should work closely with your treatment team to address questions or any concerns you may have.

WHAT IS SOFT TISSUE SARCOMA?

Soft tissue sarcoma is a type of cancer that develops in the soft tissues of the body, such as fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. Soft tissue sarcomas usually develop in the arms or legs, but they can occur anywhere in the body, including the trunk, head, neck, internal organs, and abdomen.



WHAT IS YONDELIS® (trabectedin)?

YONDELIS® (yon-DEL-ess) is a prescription medicine used to treat adults with liposarcoma or leiomyosarcoma that can't 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.

How will I receive YONDELIS®?

YONDELIS® is given every 3 weeks by an intravenous (IV) infusion 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.

You will also be given a steroid medicine before each treatment with YONDELIS® to help reduce your risk of certain side effects.

If you experience any side effects, your healthcare provider may recommend dose delays or dose reductions to ensure that you receive the most appropriate dose of YONDELIS®. If you have any side effects that are severe, your healthcare provider may stop your treatment with YONDELIS®.

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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 tell my healthcare provider before receiving YONDELIS®?

Tell your healthcare provider about all of your medical conditions, including liver or kidney problems, and if you are pregnant or plan to become pregnant. YONDELIS® can harm your unborn baby. You should not become pregnant or 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.

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®.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

What is YONDELIS® (trabectedin)?

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.

IMPORTANT SAFETY INFORMATION

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.

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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 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

INDICATION AND IMPORTANT SAFETY INFORMATION (cont)

- **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 healthcare provider 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.
- **Capillary leak syndrome.** YONDELIS[®] can cause fluid to leak from the blood vessels into the body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can cause you to have symptoms that may lead to death. Tell your healthcare provider right away if you develop swelling, dizziness or lightheadedness with or without a sudden drop in blood pressure.

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

Please read Important Safety Information on the following pages and [click here](#) to read the full Prescribing Information for YONDELIS[®].

- 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

Please [click here](#) to see Important Product Information.

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What are the most common side effects of YONDELIS[®] (trabectedin)?

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), decreased platelet cell counts (cells which help blood to clot), and changes in liver or kidney function blood tests.

Tell your healthcare provider if you feel more tired or look pale, or if you bruise easily or bleed.

What are the possible serious side effects of YONDELIS[®]?

YONDELIS[®] may cause serious side effects, including:

- **Severe infections due to decreased white blood cells.** Call your healthcare provider right away if you develop fever or other signs of infection
- **Severe muscle problems (rhabdomyolysis).** 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 the whites of your eyes, have pain in your upper-right stomach area (abdomen), nausea, vomiting, or if you generally do not feel well, have a problem with concentration, or experience confusion or sleepiness
- **Heart muscle problems, including heart failure.** Tell your healthcare provider right away if you develop

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new-onset 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.** Tell your healthcare provider or nurse 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
- **Allergic reaction.** Some patients have had allergic reactions to YONDELIS®. Signs of an allergic reaction can include difficulty breathing, chest tightness, wheezing, swelling of the lips, or skin rash
- **Capillary leak syndrome.** Tell your healthcare provider right away if you develop swelling, dizziness or lightheadedness with or without a sudden drop in blood pressure

Also, tell your healthcare provider if you have any other side effect that bothers you or that does not go away.



These are not all the possible side effects of YONDELIS®. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Janssen CarePath

Get Support on Your Treatment Path

Janssen CarePath is here to help answer your questions about your treatment with YONDELIS® (trabectedin). Once you and your doctor have decided that YONDELIS® is right for you, we will help you find resources you may need to get started and stay on track. We will give you information on your insurance coverage, potential out-of-pocket costs, and treatment support, and identify options that may help make your treatment more affordable.

Knowing that you may have questions, a Janssen CarePath Care Coordinator is available to offer one-on-one personalized assistance with:

Paying for YONDELIS®

Janssen CarePath can identify cost support options that may help with managing your out-of-pocket costs for YONDELIS®—whether you have commercial or private health insurance, government coverage such as Medicare or Medicaid, or have no insurance coverage.

- Janssen CarePath Savings Program for eligible patients with commercial or private health insurance
- Information about other resources that may help with your out-of-pocket medication costs, including Medicare resources and independent foundations[†]

[†]Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. This information is provided as a resource for you. We do not endorse any particular foundation.

Getting Started

A personally assigned Janssen CarePath Care Coordinator will work closely with you and your doctor to help get you started by:

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Reviewing your health plan benefits to help answer questions you may have about insurance coverage for YONDELIS®



Offering treatment education resources



Providing transportation assistance information and referral to independent organizations that provide assistance with costs associated with travel to and from treatment

Staying on Track

We understand how important it is for you to get YONDELIS® as your doctor prescribed. That's why we've created some tools that may help you stay on track with your YONDELIS® treatment:

- Personalized appointment reminders
- Information about Advocacy Connector, a Janssen-sponsored resource that connects patients and caregivers to national and state-specific advocacy groups that offer resources that may be relevant to your needs.

Visit **advocacyconnector.com**.

Now that you have begun the journey with your YONDELIS® treatment, please know we are here to help.

Contact Janssen CarePath to get help today

For more information, visit

JanssenCarePath.com/YONDELIS

or

call your dedicated Care Coordinator

844-YONDELIS (966-3354)

Monday through Friday | 8:00 AM to 8:00 PM ET.

Information about your insurance coverage, cost support options, and treatment support is given to you by service providers for Janssen CarePath. The information you get does not require you to use any Janssen product. Janssen CarePath cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.



TO LEARN MORE, PLEASE VISIT
WWW.YONDELIS.COM/PATIENT

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