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Trabectedin: Patient drug information

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(For additional information see "Trabectedin: Drug information")

Brand Names: US Yondelis

Brand Names: Canada Yondelis

What is this drug used for?

- · It is used to treat soft tissue sarcoma.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to trabected or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- · If you have liver disease.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, or seizures. There are many drugs that must not be taken with this drug.
- · If you are taking St. John's wort. Do not take St. John's wort with this drug. This drug may not work as well.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

• Tell all of your health care providers that you take this drug. This includes your doctors, nurses,

pharmacists, and dentists.

- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- You will need to have heart function tests while taking this drug. Talk with the doctor.
- Talk with your doctor before getting any vaccines. Use with this drug may either raise the chance of an infection or make the vaccine not work as well.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance
 of getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a
 low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or
 sore throat. Talk with your doctor.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- If you have upset stomach, throwing up, loose stools (diarrhea), or are not hungry, talk with your doctor. There may be ways to lower these side effects.
- Avoid grapefruit and grapefruit juice.
- This drug may cause a very bad and sometimes deadly problem called capillary leak syndrome (CLS). CLS may lead to low blood pressure and harm to the body. It may also lead to a heartbeat that is not normal, chest pain or pressure, heart attack, lung or breathing problems, bleeding or lower blood flow in the stomach or bowel, kidney problems, swelling, or feeling confused. Talk with the doctor.
- If you are a man and have sex with a female who could get pregnant, protect her from pregnancy during care and for 5 months after care ends. Use birth control that you can trust.
- If you are a man and your sex partner gets pregnant within 5 months after your care has ended, call your doctor right away.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- Use birth control that you can trust to prevent pregnancy while taking this drug and for at least 2 months after your last dose.
- If you get pregnant while taking this drug or within 2 months after your last dose, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, lightcolored stools, throwing up, or yellow skin or eyes.
- Not able to focus.
- · Feeling confused.

- · Feeling very tired or weak.
- Any unexplained bruising or bleeding.
- Pale skin.
- Wheezing.
- · Dizziness or passing out.
- Swelling.
- A certain muscle problem (rhabdomyolysis) has happened with this drug. Rarely, this has led to organ problems and death. Call your doctor right away if you have muscle pain or weakness.
- Heart problems like heart failure have happened in people taking this drug. Sometimes, this has been deadly. Call your doctor right away if you have chest pain or pressure, a heartbeat that does not feel normal, shortness of breath, a big weight gain, or swelling in the arms or legs.
- This drug may cause tissue damage if the drug leaks from the vein. Tell your nurse if you have any redness, burning, pain, swelling, blisters, skin sores, or leaking of fluid where the drug is going into your body.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Upset stomach or throwing up.
- · Feeling tired or weak.
- · Headache.
- Hard stools (constipation).
- Loose stools (diarrhea).
- Not hungry.
- Joint pain.
- · Not able to sleep.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- It is given as an infusion into a vein over a period of time.
- Other drugs may be given before this drug to help avoid side effects.

What do I do if I miss a dose?

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 16067 Version 86.0