

## Trabectedin (Yondelis)

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### About This Medicine

TRABECTEDIN (tra BEK te din) treats sarcoma, a cancer that occurs in bone and connective tissues, such as fat, muscle, and blood vessels. It works by slowing down the growth of cancer cells. It is given in the vein (IV).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Tiredness
- Swelling in your legs, ankles, and/or feet
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Decrease in a blood protein called albumin
- Headache
- Changes in your kidney function
- Trouble breathing

**Note:** Each of the side effects above was reported in 20% or greater of people treated with trabectedin. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- Neutropenic fever and sepsis- a serious illness from infection. Neutropenic fever is a type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.

- Changes in your liver function which can cause liver failure.
- Congestive heart failure and other changes in your heart's ability to pump blood properly, which can be life-threatening.
- Rhabdomyolysis - damage to your muscles which may release proteins in your blood and affect how your kidneys work, which can be life-threatening. You may have severe muscle weakness and/or pain, or dark urine.
- A syndrome where fluid and protein can leak from your blood vessels into your tissues, which can be life-threatening. This can cause a decrease in your blood protein level and blood pressure and fluid can accumulate in your tissues and/or lungs.
- Skin and tissue irritation including redness, pain, warmth, or swelling at the IV site if the medicine leaks out of the vein and into nearby tissue. It may cause tissue necrosis (death) more than a week after your infusion.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## Important Information

- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day..
- Allergic reactions, including anaphylaxis, are rare but may happen in some people. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with trabectedin. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking trabectedin as this may lower the levels of the medicine in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Fast breathing
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- A headache that does not go away
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy



- No bowel movement in 3 days or when you feel uncomfortable
- Decreased or very dark urine
- Unexplained muscle pain, tenderness or weakness
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of rhabdomyolysis such as decreased or very dark urine, muscle pain in the shoulders, thighs, or lower back; muscle weakness or trouble moving arms and legs.
- Swelling of the legs, ankles, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- While you are getting this medicine, please tell your care team right away if you have any pain, redness, or swelling at the site of the IV infusion.
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for at least 2 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for at least 5 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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