

Trabectedin (Yondelis)

About This Medicine

Trabectedin is used to treat cancer. It is given in the vein (IV).

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 patients 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 medical 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 lifethreatening.
- 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. Very rarely it may cause tissue necrosis (death).

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

Important Information

 Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.

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 doctor or nurse 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 nurse 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 nurse or doctor 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 nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your doctor or nurse 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 doctor's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist 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 doctor or pharmacist 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 the Doctor

Call your doctor or nurse 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 nurse right away if you have any pain, redness, or swelling at the site of the IV infusion.
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- Pregnancy warning: This medicine can have harmful effects on the unborn baby. Women of
 childbearing potential should use effective methods of birth control during your cancer treatment
 and for at least 2 months after stopping treatment. Men with female partners of childbearing
 potential should use effective methods of birth control during your cancer treatment and for at
 least 5 months after stopping treatment. Let your doctor know right away if you think you may be
 pregnant or may have impregnated your partner.
- **Breastfeeding warning**: Women should not breastfeed during treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- Fertility warning: In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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