

Trabectedin (Yondelis®)

About This Drug

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 (fatigue), and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Tiredness
- Swelling in your legs, ankles, and/or feet
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Increase in creatine phosphokinase, which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- 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. Not all possible side effects are included above.

Warnings and Precautions

- Fever, in the setting of decreased white blood cells is a serious condition which can rarely be life-threatening.
- Changes in your liver function which can cause liver failure
- Changes in the tissue of the heart and congestive heart failure, which can be life-threatening. Some changes may happen that can cause your heart to have less ability to pump blood.
- Rhabdomyolysis- damage to your muscles which may release proteins in your blood and affect how your kidneys work. You may have severe muscle weakness (lack of muscle strength).

- A syndrome where fluid from your veins can leak into your tissues and cause a decrease in your blood pressure and fluid to accumulate in your tissues and/or lungs
- Skin and tissue irritation including redness, pain, warmth, or swelling at the IV site if the drug 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

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

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 plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, 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 wellbeing. Please tell your doctor or nurse if you are experiencing pain.

Food and Drug Interactions

- There are no known interactions of trabectedin with food.
- 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 drug 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 drug 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
- Tiredness 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 urine, 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, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of rhabdomyolysis: Decreased urine, very dark urine, muscle pain in the shoulders, thighs, or lower back; muscle weakness or trouble moving arms and legs.
- Swelling of legs, ankles, or feet
- Weight gain of 5 pounds in one week (fluid retention)
- While you are getting this drug, 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 drug 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 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 your cancer 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 drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug 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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