



Liposomal daunorubicin/cytarabine (Vyxeos™)

About This Drug

Liposomal daunorubicin/cytarabine 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.
- Fever in the setting of decreased white blood cells, which is a serious condition that can be life-threatening
- Chills
- Abnormal heart beat
- Nausea and vomiting (throwing up)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Pain in your abdomen
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds or any other unusual bleeding
- Tiredness
- Swelling of your legs, ankles and/or feet
- Bacterial infection in the blood
- Decreased appetite (decreased hunger)
- Joint, bone and muscle pain
- Headache
- Trouble sleeping
- Pneumonia
- Trouble breathing
- Cough
- Rash

Note: Each of the side effects above was reported in 25% or greater of patients treated with liposomal daunorubicin/cytarabine. Not all possible side effects are included above.

Warnings and Precautions

- Severe abnormal bleeding, which can be life-threatening
- Changes in your heart function
- Allergic reactions, including anaphylaxis are rare but may happen in some patients and can be life-threatening. 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.
- 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. Rarely it may cause tissue necrosis (death).
- If you have Wilson's disease, you may be at increased risk of accumulating more copper in your body.

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 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 or stop lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.

- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories
- If you get 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.
- 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.
- If you are having trouble sleeping, talk to your nurse or doctor on tips to help you sleep better.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Drug Interactions

- There are no known interactions of liposomal daunorubicin/cytarabine with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. 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.

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 100.5 F (38 C) or higher
- Chills
- Headache that does not go away
- Confusion
- Fast breathing, wheezing and/or trouble breathing
- Cough
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red, or black/tarry)
- Coughing up blood
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day

- Pain in your mouth or throat that makes it hard to eat or drink
- 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
- Pain in your abdomen that does not go away
- Weight gain of 5 pounds in one week (fluid retention)
- A new rash or a rash that is not relieved by prescribed
- 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
- 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 child bearing potential should use effective methods of birth control during your cancer treatment and for at least 6 months after treatment. Men with female partners of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 6 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:** It is not known if this drug passes into breast milk. For this reason, Women should not breastfeed during treatment and for at least 2 weeks after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, 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 banking.

Revised October 2018