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Pegylated liposomal doxorubicin: Patient drug information

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(For additional information see "Pegylated liposomal doxorubicin: Drug information")

Brand Names: US Doxil; Lipodox 50; Lipodox [DSC]

Brand Names: Canada Caelyx

Warning

- This drug may cause very bad heart problems like heart failure. This can happen during care or months to years after you get this drug. Sometimes, these heart problems will not go away or may be deadly. The chance of heart problems may be raised if you are using other drugs that may cause heart problems or if you have ever had heart problems or radiation to the chest area, or if you have ever had this drug or other drugs like this one. Ask your doctor if you are not sure if any drugs you take may cause heart problems. Your chance of heart problems depends on your dose of this drug and your health problem. Heart problems may happen even if you do not have any risk factors. In children, the chance of heart problems later in life is raised. Call your doctor right away if you have cough, fast or slow heartbeat, a heartbeat that does not feel normal, swelling in the arms or legs, shortness of breath, sudden weight gain, or feeling very tired or weak.
- Side effects like flushing, shortness of breath, wheezing, swelling of the face, headache, chills, back pain, chest pain, chest or throat tightness, fever, fast heartbeat, itching, blue or gray skin, very bad dizziness, or passing out have happened with this drug during the infusion. Most of the time, these side effects happen with the first infusion and go away within a few hours to a day after the infusion is stopped. Sometimes, these reactions have been very bad and even life-threatening or deadly. Tell your doctor right away if you have any of these signs.

What is this drug used for?

It is used to treat cancer.

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

- If you have an allergy to doxorubicin 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 are breast-feeding or plan to breast-feed.

This drug may interact with other drugs or health problems.

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 your heart checked before starting this drug. This includes an ECG. Talk with your doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- 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.
- To help with mouth sores, use a soft toothbrush or cotton swabs and rinse the mouth. Do not use mouth rinses that have alcohol in them.
- If you have had daunorubicin, doxorubicin, epirubicin, idarubicin, or mitoxantrone before, talk with your doctor.
- This drug may add to the chance of getting some types of cancer. Talk with the doctor.
- Cases of mouth cancer have happened in people who have used this drug long-term (more than 1 year). These cancers have happened during care with this drug and up to 6 years after the last dose. Your doctor will check your mouth during care with this drug. Call your doctor right away if you have mouth pain, sores, or ulcers.
- 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.
- This drug may affect being able to father a child. In some people, this may go back to normal but may take some time. 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 6 months after care ends. Use birth control that you can trust.
- If you are a man and your sex partner gets pregnant while you take this drug or within 6 months after your last dose, call your doctor right away.
- Periods may stop in women treated with this drug. This may not go back to normal. Women treated with this drug may go through menopause at a younger age than normal. Talk with your doctor.
- This drug may cause fertility problems. This may affect being able to have children. 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 during care and for 6 months after care ends.
- If you get pregnant while taking this drug or within 6 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 bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.
- Chest pain or pressure.
- Very upset stomach or throwing up.
- A big weight loss.
- Bone pain.
- · Night sweats.
- A burning, numbness, or tingling feeling that is not normal.
- · Redness or irritation of the palms of hands or soles of feet.
- Mouth irritation or mouth sores.
- Feeling very tired or weak.
- Blood in the urine.
- This drug may irritate the vein. It may burn the skin if the drug leaks from the vein when it is given. Tell your nurse if you have any redness, burning, pain, swelling, 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:

- · Feeling tired or weak.
- · Hard stools (constipation).
- · Loose stools (diarrhea).
- Upset stomach or throwing up.
- Not hungry.
- · Back pain.
- · Headache.
- · Hair loss.
- Throat irritation.
- · Weight loss.
- Urine and other body fluids may change to an orange or red color. This is normal.

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.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.

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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