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Idarubicin

pronounced as (eye da rue' bi sin)

IMPORTANT WARNING:

Idarubicin should be administered only into a vein. However, it may leak into surrounding tissue causing severe irritation or damage. Your doctor or nurse will monitor your administration site for this reaction. If you experience any of the following symptoms, call your doctor immediately: pain, itching, redness, swelling, blisters, or sores in the place where the medication was injected.

Idarubicin may cause serious or life-threatening heart problems at any time during your treatment or months to years after your treatment has ended. Your doctor will order tests before and during your treatment to see if your heart is working well enough for you to safely receive idarubicin. These tests may include an electrocardiogram (ECG; test that records the electrical activity of the heart) and an echocardiogram (test that uses sound waves to measure your heart's ability to pump blood). Your doctor may tell you that you should not receive this medication if the tests show your heart's ability to pump blood has decreased. Tell your doctor if you have or have ever had any type of heart disease or radiation (x-ray) therapy to the chest area. Tell your doctor and pharmacist if you are taking or have ever received certain cancer chemotherapy medications such as daunorubicin (cerubidine), doxorubicin (Doxil), epirubicin (Ellence), mitoxantrone (Novantrone), cyclophosphamide (Cytoxan), or trastuzumab (Herceptin). If you experience any of the following symptoms, call your doctor immediately: shortness of breath; difficulty breathing; swelling of the hands, feet, ankles or lower legs; or fast, irregular, or pounding heartbeat.

Idarubicin can cause a severe decrease in the number of blood cells in your bone marrow. This may cause certain symptoms and may increase the risk that you will develop a serious infection or bleeding. If you experience any of the following symptoms, call your doctor immediately: fever, sore throat, ongoing cough and congestion, or other signs of infection; unusual bleeding or bruising; bloody or black, tarry stools; bloody vomit; or vomiting blood or brown material that resembles coffee grounds.

Tell your doctor if you have or have ever had kidney or liver disease. Your doctor may tell you that you should not receive this medication or may change your dose if you have kidney or liver disease.

Idarubicin should be given only under the supervision of a doctor with experience in the use of chemotherapy medications.

Why is this medication prescribed?

Idarubicin is used to treat acute myelogenous leukemia (AML; a type of cancer of the white blood cells) in combination with other medications. Idarubicin is in a class of medications called anthracyclines. It works by slowing or stopping the growth of cancer cells in your body.

How should this medicine be used?

Idarubicin comes as a solution (liquid) to be injected intravenously (into a vein) over 10 to 15 minutes by a doctor or nurse in a medical facility along with other chemotherapy medications. It is usually given once a day for 3 days. Your doctor may need to delay your treatment or adjust your dose if you experience certain side effects. It is important for you to tell your doctor how you are feeling during your treatment with idarubicin.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving idarubicin,

- tell your doctor and pharmacist if you are allergic to idarubicin, any other medications, or any of the ingredients in idarubicin injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have previously received radiation therapy or have or have ever had heart disease or if you have an infection, blood-clotting problems, or anemia (decreased amount of red blood cells in the blood).
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. You should not become pregnant or breast-feed while you are receiving idarubicin injection. If you become pregnant while receiving idarubicin, call your doctor. Idarubicin may harm the fetus.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Idarubicin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea

- sores in the mouth and throat
- stomach pain
- headache
- joint pain
- hair loss
- rash
- redness and blisters on the palms and soles

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- seizures
- hives
- dizziness
- fainting
- pale skin
- difficulty urinating
- yellowing of the skin or eyes

Idarubicin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- nausea
- vomiting
- severe stomach pain
- sores in the mouth and throat
- fever, sore throat, chills, or other signs of infection

- unusual bleeding or bruising
- black and tarry stools
- red blood in stools
- bloody vomit
- vomited material that looks like coffee grounds

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to idarubicin.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Idamycin[®] PFS

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