PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]IDARUBICIN

Idarubicin Hydrochloride Injection

Read this carefully before you start taking **IDARUBICIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **IDARUBICIN**.

Serious Warnings and Precautions

- **Myelosuppression (bone marrow suppression leading to low blood cell and platelet counts):** Treatment with IDARUBICIN can cause myelosuppression. This can lead to decreased white blood cells, decreased blood platelets, decreased red blood cells, fever, infections, hemorrhage (bleeding), tissue hypoxia, or even death.

- **Cardiotoxicity (damage to the heart):** Treatment with anthracyclines, such as IDARUBICIN, can cause heart problems, especially in children. This can include:
  - irregular heartbeat rhythm or rate (arrhythmias),
  - atrioventricular and bundle branch block (partial or complete interruption of the electrical signal to the heart),
  - myocarditis/pericarditis (inflammation of the heart muscle and lining around the heart),
  - congestive heart failure (CHF; heart does not pump blood as well as it should); symptoms include:
    - dyspnea (shortness of breath),
    - pulmonary edema (excess fluid in the lungs), dependent edema (swelling in the lower body),
    - hepatomegaly (liver enlargement), oliguria (less pee than usual), ascites (fluid in the abdomen), and
    - pleural effusion (fluid around the lungs).

Your healthcare professional will monitor and assess the profile of your blood and how your heart is working before and during your treatment with IDARUBICIN. If you develop myelosuppression or heart problems, they will act quickly to avoid and treat any unwanted effects and may stop your treatment if necessary. See the **Serious side effects and what to do about them table**, below, for more information on these and other serious side effects.

What is IDARUBICIN used for?

IDARUBICIN is used alone or in combination with other anti-cancer drugs:

- as a first line treatment for adults with acute non-lymphocytic leukemia (ANLL).
- as a treatment for adults with ANLL that has returned after treatment (relapsed) or does not respond to treatment (refractory).
- as a second line treatment for adults and children with acute lymphocytic leukemia (ALL).

How does IDARUBICIN work?

IDARUBICIN is an anti-cancer (cytotoxic) chemotherapy medication. It works by killing rapidly dividing cells, such as cancer cells, by interfering with the growth and division of these cells.

What are the ingredients in IDARUBICIN?

Medicinal ingredient: Idarubicin hydrochloride

Non-medicinal ingredients: Glycerol, hydrochloric acid, and water for injection

IDARUBICIN comes in the following dosage forms:

Preservative-Free Solution for injection: 1 mg / mL (in 5 mL, 10 mL, and 20 mL vials)

Do not use IDARUBICIN if:

- you are allergic to idarubicin, any of the other ingredients in IDARUBICIN, or its container.
- you are allergic to other anti-cancer drugs known as anthracyclines and anthracenediones (e.g., epirubicin, daunorubicin, mitoxanthrone, and mitomycin C).
- you have uncontrolled infections.
- you have persistent low blood cell and platelet counts (myelosuppression).
- you have severe liver problems.
- you have severe kidney problems.
- you have or have had severe heart problems including heart failure, a recent heart attack, or arrhythmia (irregular heartbeat).
- you have been treated with a maximum cumulative dose of idarubicin, doxorubicin, daunorubicin, epirubicin, other anthracyclines or other anthracenediones. If you are unsure ask your healthcare professional.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IDARUBICIN. Talk about any health conditions or problems you may have, including if you:

- have low blood cell counts;
- have an infection;
- have had radiation therapy (radiotherapy);
- Are pregnant or planning to become pregnant
- Are breast-feeding or planning to breast-feed
- have had unwanted effects from previous cancer treatment;
- have or have had heart and blood problems;
- have gastrointestinal problems (e.g., gastrointestinal bleeding or perforation);
- have liver problems;
- have kidney problems;
- are taking other anti-cancer medications (e.g., anthracyclines such as trastuzumab and anthracenediones);
- are taking medications that affect your heart (e.g., amlodipine, diltiazem, and verapamil);
- have had acute leukemia (a type of cancer of the blood or bone marrow) in the past;
- have had previous condition(s) or have previously taken medications that are known to lead to gastrointestinal problems. If you are unsure ask your healthcare professional;
- are planning to get a vaccine and have a compromised immune system. You may be at a higher risk of developing serious or fatal infections;
- are over the age of 60 years of age.

Other warnings you should know about:

IDARUBICIN can cause serious side effects including:

- **Hyperuricemia (high uric acid levels in the blood):** Treatment with idarubicin can result in a large number of cancer cells dying and releasing their contents into the blood (also known as tumour lysis syndrome). This can lead to hyperuricemia. Your healthcare professional will monitor the profile of your blood (e.g., levels of uric acid, potassium, calcium, phosphate, and creatinine) before your treatment. They will suggest ways to prevent hyperuricemia (e.g., by staying hydrated), which may also help minimize the effects of tumour lysis syndrome.

- **Injury around the site of injection:** Extravasation (leakage of the injected solution that causes damage around the site of injection) can occur when IDARUBICIN is given to you. This can lead to local pain, severe tissue lesions (e.g., a lump, bump, sore, or patch), severe local tissue necrosis (tissue death), and phlebosclerosis (a diseases characterized by thickening or hardening of the walls of veins). If you develop extravasation, your healthcare professional will stop your treatment right away.

- **Blood clots:** The use of cytotoxic agents, such as idarubicin, has been reported to cause blood clots and thrombophlebitis (inflammation caused by blood clots, usually in the leg). Your healthcare professional will monitor your health for signs and symptoms of blood clots.

- **Secondary leukemia (a type of cancer that develops from previous disorders or exposure to cytotoxic agents):** Treatment with anthracyclines (cytotoxic agents), such as IDARUBICIN, can lead to secondary leukemia. Your healthcare professional will monitor you for signs and symptoms of secondary leukemia.

- **Gastrointestinal problems:** Treatment with IDARUBICIN can cause gastrointestinal problems including:
    - mucositis (inflammation and ulceration of the mucous membranes lining the digestive tract),
    - gastrointestinal perforation (a hole in the wall of your stomach or bowels), and
    - gastrointestinal bleeding (bleeding anywhere along the GI tract between mouth and anus).

  Your healthcare professional will monitor and assess your health before and during your treatment with IDARUBICIN.

- **Kidney problems:** Treatment with IDARUBICIN can cause kidney problems. You will have regular tests done before and during your treatment with IDARUBICIN. These tests will tell your healthcare professional how your kidney is working.

See the **Serious side effects and what to do about them table**, below, for more information on these and other serious side effects.

Pregnancy and breastfeeding:

- Avoid becoming pregnant while taking IDARUBICIN. If you are able to get pregnant or think you are pregnant, there are specific risks for your unborn baby that you must discuss with your healthcare professional.
- You and your partner should use effective birth control while taking IDARUBICIN and for at least 6.5 months after your last dose.
- If you become pregnant or think you are pregnant while taking IDARUBICIN, tell your healthcare professional right away.
- If you are breastfeeding or plan to breastfeed. It is not known if IDARUBICIN passes into your breast milk. Do not breastfeed during treatment with IDARUBICIN or for 14 days after your last dose. Talk to your healthcare professional about the best way to feed your baby during this time.

Fertility:

- IDARUBICIN is a cytotoxic agent and can cause fertility impairment. If you are a male, it can damage the DNA in your sperm. You and your partner should use effective birth control while taking IDARUBICIN and for at least 3.5 months after your last dose.
- If you want to become pregnant or father a child after treatment with IDARUBICIN, talk to your healthcare professional about fertility preservation options before starting your treatment.
- Speak to your healthcare professional if you decide to have a child after completing your treatment with IDARUBICIN. Your healthcare professional will advise you on whether genetic counselling would be appropriate for you.

Check-ups and testing:
You will have regular visits with your healthcare professional before, during, and after your treatment. They may do tests that will assess the profile of your blood, and how your heart, liver, and kidneys are working. This will help your healthcare professional assess your health and tell them how IDARUBICIN is affecting you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IDARUBICIN:

- chemotherapy medicines used to treat different types of cancers such as:
    - anthracyclines
    - anthracenediones
    - alkylating agents (e.g., cyclophosphamide)
    - antineoplastic agents (e.g., etoposide, cytarabine, and fludarabine)
    - cardiotoxic drugs (e.g., cyclophosphamide and paclitaxel)
    - cardioactive compounds (e.g., amlodipine, diltiazem, and verapamil)
- medicines known as corticosteroids that are used to reduce inflammation and suppress the immune system (e.g., dexamethasone).

How to take IDARUBICIN:

Your healthcare professional will prepare and give you IDARUBICIN. You may receive IDARUBICIN through your veins (i.e., “intravenously” or “IV”). However, if you are getting multiple injections, your healthcare professional may use a catheter (thin tube) or port to inject medicines into your body.

Usual dose:

Your healthcare professional will determine the right dose, length, and cycle of IDARUBICIN for you based on:

- your medical condition(s),
- treatment goals,
- the medicines (including chemotherapy) you are getting, and
- how your body responds to those medicines.

Overdose:

If you think you, or a person you are caring for, have been given too much IDARUBICIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your scheduled treatment with the drug, contact your doctor as soon as possible to schedule your next treatment.

What are possible side effects from using IDARUBICIN?

These are not all the possible side effects you may have when taking IDARUBICIN. If you experience any side effects not listed here, tell your healthcare professional.

Some side effects may include:

- hair loss (alopecia), which is temporary and usually starts to grow back within 2 or 3 months after you have finished your treatments.
- red colouration of your urine for 1 to 2 days after being given IDARUBICIN.
- dehydration.
- inflammation of the skin where radiation was received (radiation recall reaction).
- hot flashes.
- skin and nail changes or colouration.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Infection as a result of low white blood cell count: fever, chills, sweating, sore throat, nausea, vomiting, diarrhea, generally feeling unwell, coughing, redness or swelling around a cut, wound at catheter		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
site, a burning feeling when you urinate, unusual vaginal itching or discharge			
Anemia (decreased number of red blood cells): weakness, dizziness, shortness of breath, fatigue, loss of energy, irregular heartbeats, pale complexion		✓	
RARE			
Cardiovascular problems (heart and blood problems including cardiac toxicity, congestive heart failure, low blood platelets)**:** rapid, slow or irregular heartbeat, chest pain, swelling of the ankles, legs or feet, shortness of breath, heart stops beating, palpitations, cough, fluid retention, lack of appetite, nausea, bruising or bleeding for longer than usual if you hurt yourself		✓	
Injection site reactions: pain, sores, burning at injection site, blistering, itching, redness, severe skin damage, tenderness, warmth in the area around the injection		✓	
Hemorrhage (increased bleeding from the blood vessels): dark urine or dark/bloody stool, unexplained bruising, headaches, weakness, tingling or numbness in the arms or legs, nausea, vomiting, changes in vision or balance		✓	
Colitis (bowel inflammation) or digestive tract bleeding: bloody stools, bloody vomit, severe or		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
persistent diarrhea, abdominal pain, nausea and vomiting, fever			
UNKNOWN FREQUENCY			
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain, swelling, nausea, vomiting, unusual dark urine, or unusual tiredness		✓	
Mucositis (inflammation and ulceration of the mucous membranes lining the digestive tract): painful, red, shiny or swollen gums, tongue, mouth or throat sores, blood in the mouth, difficult or painful swallowing or talking, dry mouth, mild burning, or pain when eating food		✓	
Myelosuppression (a large decrease in the production of blood cells and platelets by the bone marrow): bleeding, bruising, chills, fatigue, fever, infections, weakness, shortness of breath, or other signs of infection		✓	
Gastrointestinal problems: stomach pain, decreased appetite, diarrhea, nausea, vomiting, vomiting of blood, black stools, constipation, heartburn, swelling or bloating of the abdomen, blood in stool		✓	
Hyperuricemia (high uric acid levels in the blood): joint stiffness or pain, redness,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
swelling, or difficulty moving your joints			
Sepsis and septic shock (infection of the blood): fever, dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, or rapid heartbeat		✓	
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives, rashes, swelling of the face, lips, tongue or throat		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

IDARUBICIN should be stored at 2°C to 8°C. Protect from light. Discard unused portion.

Keep out of reach and sight of children.

If you want more information about IDARUBICIN:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised: SEP 08, 2022