

PART III: CONSUMER INFORMATION

**PrIDARUBICIN
Idarubicin hydrochloride injection**

This leaflet is part III of a three-part "Product Monograph" published when IDARUBICIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about IDARUBICIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

IDARUBICIN alone or in combination with other anticancer drugs is used in the treatment of:

- § Acute non-lymphocytic leukemia (ANLL) as a first line in adult patients
- § Acute lymphocytic leukemia (ALL) as a second line in adults and children.

What it does:

IDARUBICIN is a cancer drug (chemotherapy drug) which works by killing rapidly dividing cells, such as cancer cells. This action can affect normal cells as well.

In people with leukemia, the bone marrow produces abnormal white blood cells. The abnormal white cells are cancer cells (leukemia cells).

When it should not be used:

Do not use the drugs if you:

- are allergic to idarubicin or any of the ingredients of the drug or its container (**see What the important non-medicinal ingredients are**),
- are allergic to other anthracyclines or anthracenediones such as epirubicin, daunorubicin, mitoxanthrone or mitomycin.
- have persistent low blood count (myelosuppression)
- have severe liver, renal or heart disease
- have recent heart attack
- have severe irregular heartbeat
- have history of severe cardiac disease
- have uncontrolled infections
- have been treated with a maximum cumulative dose of idarubicin, doxorubicin, daunorubicin, epirubicin or other anthracyclines or anthracenediones.

What the medicinal ingredient is:

Idarubicin hydrochloride is the active ingredient.

What the important non-medicinal ingredients are:

IDARUBICIN 1mg/mL (idarubicin hydrochloride injection):

Glycerol USP/Ph.Eur.
Hydrochloric acid
Water for Injection USP

What dosage forms it comes in:

IDARUBICIN 1mg/mL (idarubicin hydrochloride injection) is a clear red-orange sterile solution to be given intravenously.

WARNINGS AND PRECAUTIONS

IDARUBICIN should be given under the supervision of a doctor experienced with the use of anticancer drugs.

IDARUBICIN should not be given to patients with the following conditions:

- **A low blood count (bone marrow suppression induced by previous drug therapy or radiotherapy);**
- **A heart disease and/or previous treatment with anthracyclines (cardiotoxic drugs)**

BEFORE you use IDARUBICIN talk to your doctor if you:

- Have low blood cell counts;
- Have heart disease, recent heart attack or irregular heartbeat;
- Have an infection;
- Have had radiotherapy to chest area;
- Are taking calcium channel blockers, such as amlodipine, diltiazem, verapamil;
- Are pregnant or planning to become pregnant
- Are breast-feeding or planning to breast-feed
- Have been previously treated with IDARUBICIN or other anti-cancer drugs, including anthracyclines (cardiotoxic drugs).

As IDARUBICIN may be harmful to an unborn child, women should be advised to avoid becoming pregnant. Effective contraceptive methods should be used.

Tell your doctor right away if you become pregnant during treatment. If you have been nursing, you should stop before starting treatment with IDARUBICIN. Ask your baby's doctor to recommend a formula that would be best for your baby.

As IDARUBICIN may cause fertility impairment and damage chromosomes in sperm, men undergoing treatment with IDARUBICIN, should use effective contraceptive methods.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you have or recently have taken any other medicines including medicines bought without prescription.

Drugs that may interact with IDARUBICIN include: cytarabine, other anthracyclines, anthracenediones and calcium channel blockers such as amlodipine, diltiazem or verapamil.

Other drugs that may be used in therapy with IDARUBICIN may increase the chance of toxic effects include: cyclophosphamide, fludarabine, etoposide, paclitaxel.

Talk to your doctor before you receive a vaccine while treated with IDARUBICIN, as the combination may result in a serious infection in patients with a compromised immunity (ie patients taking oral corticosteroids, transplanted patients, elderly patients).

PROPER USE OF THIS MEDICATION

How is IDARUBICIN given?

You may receive IDARUBICIN through a vein in the arm (“intravenously” or “IV”) by your doctor or nurse, usually in the hospital, outpatient department or clinic.

If you are getting many injections, for your convenience, your doctor may insert a catheter (thin tube) or port into a large vein in your body that is placed there as long as it is needed. Medicines get injected through the catheter or port rather than directly into a vein.

How much time does it take to get a treatment with IDARUBICIN?

It usually takes about 5-10 minutes to inject IDARUBICIN. However, you may get other medicines before or after IDARUBICIN, so your entire treatment may last an hour or longer.

How long will I need treatment?

Your doctor will determine the length of your treatment based on your treatment goals, the medicines you receive, and how your body responds to those medicines.

Your treatment cycle will depend on your medical condition and the other chemotherapy medicines you are getting. IDARUBICIN is usually given once a day for 3 consecutive days.

Overdose

If you think you are given more IDARUBICIN than you should, contact your doctor, nurse, or poison control centre immediately.

Missed dose

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, IDARUBICIN can have side effects.

Common side effects include:

- Hair loss, which is temporary and usually starts to grow back within 2 or 3 months after you have finished your treatments.
- Infection, as a result of low white blood cell count. The signs of infection include fever over 38°C (100°F), chills or sweating, sore throat or coughing, redness or swelling around a cut, wound or a catheter site, a burning feeling when you urinate, unusual vaginal itching or discharge.
- Nausea and vomiting
- Fatigue, or feeling tired
- Mouth sores
- Anemia, or low red blood cell count
- Red coloration of your urine for 1 to 2 days after administration during active therapy
- Diarrhea with dehydration and symptoms such as skin flushed, dry and pale, less urination
- Sensitivity of irradiated skin
- Hot flashes
- Skin and nail changes or colouration, tingling sensation
- Rash/itch/redness skin allergy

Rare side effects include:

- Severe adverse events such as local tissue damages due to leakage of IDARUBICIN from your vein into surrounding tissues with intravenous injection might be observed.
- Serious heart problems in a small percentage of patients
- Urticaria (hives)

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist

