

PART III: CONSUMER INFORMATION**DOXORUBICIN****Doxorubicin hydrochloride injection**

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

ABOUT THIS MEDICATION**What the medication is used for:**

DOXORUBICIN is used alone and in combination with other anti-cancer medication to produce regression of tumor in several cancer conditions.

For the treatment of superficial bladder tumor, DOXORUBICIN is administered directly in the bladder.

What it does:

DOXORUBICIN is a chemotherapy drug, often used in combination with other drugs to kill cancer cells. Most chemotherapy agents (including DOXORUBICIN) work by killing rapidly dividing cells, such as cancer cells. This action can affect normal cells as well.

When it should not be used:For intravenous administration:

- Allergy to doxorubicin hydrochloride or to any ingredient in the formulation or component of the container of DOXORUBICIN;
- Allergy to other anthracyclines or anthracenediones such as epirubicin hydrochloride, daunorubicin hydrochloride, mitoxantrone or mitomycin C;
- Persistent low blood cell count (myelosuppression);
- Severe liver disease;
- Severe heart disease;
- Recent heart attack;
- Severe irregular heartbeat;
- History of severe cardiac disease;
- Previous treatment with maximum cumulative doses of doxorubicin, daunorubicin, epirubicin, idarubicin and/or other anthracyclines and anthracenediones. Accumulation of anthracycline doses may be harmful for your heart.

For intravesical administration:

- Blood in urine;
- Urinary tract infections;
- Inflammation of the bladder.

What the medicinal ingredient is:

Doxorubicin hydrochloride.

What the important non-medicinal ingredients are:

Sodium Chloride USP,
Water for Injection USP and
Hydrochloric Acid USP for pH adjustment.

What dosage form it comes in:

DOXORUBICIN injection 2 mg/mL (doxorubicin hydrochloride injection) is available in 10 mg (5mL), 50 mg (25mL) and 200 mg (100mL) contained in glass or cytosafe (polypropylene) vials.

WARNINGS AND PRECAUTIONS

If you are prescribed DOXORUBICIN it will only be given to you by doctors or nurses experienced in giving chemotherapy.

If you take DOXORUBICIN you may get:

- **Damage to the heart muscle called heart failure.** It is a decreased ability of the heart muscle to pump properly. This can lead to shortness of breath, swelling of the legs, irregular heart beat and sudden death. You are more likely to develop this as the dose is increased. It may occur during treatment or up to several years later.
- **Risk of new cancers.** You are at increased risk for getting certain blood cancers. They are called acute secondary myelogenous leukemia (AML) and myelodysplastic syndrome (MDS). This can happen 1 to 3 years after treatment with DOXORUBICIN. It is more common if you take it at higher doses or with other cancer treatments. This risk also applies to children.
- **Tissue damage.** DOXORUBICIN will cause damage if it leaks out of your vein underneath your skin. You may get blisters or sores that require skin grafts. If it hurts, burns or sting in or around the vein into which the drug is being injected, tell the doctor or nurse **IMMEDIATELY.**
- **Low blood cell counts.** DOXORUBICIN can cause a severe decrease in the number of white blood cells, red blood cells, and platelets. This means that you may bruise or bleed more easily, go into shock and need blood transfusions. You may get fever, serious infection, and need treatment in a hospital. Low blood cell counts can lead to death. Your doctor will check your blood cell counts during your treatment and after you stop it. Call your doctor right away if you get severe bleeding, fever or chills with shivering.
- **Risk of liver problems.** Tell your doctor if you have a history of liver disease. You should not take DOXORUBICIN if you have a severe liver disease.

BEFORE you use DOXORUBICIN talk to your doctor or pharmacist if:

- you have low blood cell counts;
- you have a liver disease;
- you have a heart disease, recent heart attack or irregular heartbeat;
- you are taking other drugs (including calcium channel blockers) or have been previously treated with DOXORUBICIN or other anti-cancer drugs, including anthracyclines (cardiotoxic drugs);
- you are pregnant, breast-feeding or planning to become pregnant.

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

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

INTERACTIONS WITH THIS MEDICATION

Combination chemotherapy regimens that contain other agents with similar action may lead to additive toxicity, especially with regard to bone marrow/hematologic, gastrointestinal, and cardiac effects.

Administration of live vaccines to immunosuppressed patients including those undergoing cytotoxic chemotherapy should be avoided.

Drug interactions with DOXORUBICIN and the following drugs have been reported in the literature:

- Paclitaxel;
- Phenobarbital;
- Phenytoin;
- Streptozocin;
- Cyclophosphamide;
- Cyclosporine
- 6-mercaptopurine;
- Actinomycin-D.

PROPER USE OF THIS MEDICATION***How is DOXORUBICIN given?***

You may receive DOXORUBICIN 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 over several weeks or months, 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.

Depending on your medical condition, you may also receive DOXORUBICIN by instillation into your bladder through a catheter inserted into the urinary natural tract.

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

It usually takes about 3-10 minutes to inject DOXORUBICIN. However, you may get other medicines before or after DOXORUBICIN, so your entire treatment may last an hour or longer.

If you are administered DOXORUBICIN by instillation into your bladder, the solution should generally be retained in your bladder for 1-2 hours prior to voiding.

How long will I need treatment?

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

Chemotherapy is usually given in cycles that include rest periods between treatments. The rest periods give your body a chance to build healthy new cells and regain your strength before your next treatment. DOXORUBICIN is usually given in treatment cycles of 21 days or 28 days. You may receive 1 dose of DOXORUBICIN every 3 or 4 weeks (on Day 1 of the cycle). Alternately, you may also receive DOXORUBICIN instilled into your bladder weekly for 4 weeks and then monthly. Your treatment cycle will depend on your medical condition and the other chemotherapy medicines you are getting.

Will I be able to work?

Some people work full time, while others work part time or wait until their chemotherapy treatments are finished. It depends on the type of job you have and the side effects you experience.

Is it okay to become pregnant or nurse a baby?

No. DOXORUBICIN can be harmful to an unborn child. If there is any possibility that you may become pregnant, ask your doctor about using birth control to prevent pregnancy during your treatment with DOXORUBICIN. Tell your doctor right away if you become pregnant during treatment. If you have been nursing, you should stop before starting treatment with DOXORUBICIN. Ask your baby’s doctor to recommend a formula that would be best for your baby.

What should men consider when taking DOXORUBICIN?

Men undergoing treatment with doxorubicin should use effective contraceptive methods.

What happens after treatment?

After you have completed all your chemotherapy treatments, your doctor will check you regularly to make sure the cancer has not returned.

Overdosage:

If you think you have been given more DOXORUBICIN 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, DOXORUBICIN 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.
- increased risk of 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.
- Red coloration of your urine for 1 to 2 days after administration during active therapy

Rare side effects include:

- Severe adverse events such as local tissue damages due to leakage of DOXORUBICIN from your vein into surrounding tissues with intravenous injection might be observed.
- Damage to the heart muscle, which can cause symptoms such as shortness of breath, swelling in the ankles, and fluid retention. If you have these symptoms, call your doctor right away. There are medicines to treat this condition.

DOXORUBICIN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect		Talk with your doctor or pharmacist	
		Only if severe	In all cases
Common	<ul style="list-style-type: none"> • anorexia • diarrhea • infection • hemorrhage • irregular heartbeat, chest pain, swelling of the ankles, shortness of breath / cardiac problems • pain at the site of the injection rash/itch/redness/skin allergy 	T	T T T T T
Un-common	<ul style="list-style-type: none"> • loss of monthly periods • allergy/anaphylaxis • blood clot • digestive inflammation, digestive tract bleeding (bloody stools, bloody vomit), color change of the oral mucosa • dehydration • hot flashes • shock • skin and nail changes , tingling sensation, urticaria 		T T T T T T T T

This is not a complete list of side effects. For any unexpected effects while taking DOXORUBICIN, contact your doctor or pharmacist.

HOW TO STORE IT

DOXORUBICIN 2mg/mL shall be stored under refrigeration (2-8°C), protected from light and retained in carton until time of use. Discard unused solution.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001

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