

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

DOXORUBICIN HYDROCHLORIDE FOR INJECTION USP

Doxorubicin hydrochloride injection

Read this carefully before you start taking **Doxorubicin Hydrochloride for Injection USP** and each time it is administered to you. 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 **Doxorubicin Hydrochloride for Injection USP**.

Serious Warnings and Precautions

Doxorubicin Hydrochloride for Injection USP will only be given to you by healthcare professionals experienced in giving chemotherapy.

If you take Doxorubicin Hydrochloride for Injection USP, you may get:

- **cardiomyopathy** (damage to the heart muscle), which makes it harder for your heart to pump properly. This can lead to shortness of breath, swelling of the legs, irregular heartbeat and sudden death. You are more likely to develop this as your dose is increased. It may happen during treatment or up to several years later.
- certain **blood cancers** such as acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS). This can happen 1 to 3 years after treatment with Doxorubicin Hydrochloride for Injection USP. It is more common if you take it at higher doses or with other cancer treatments. This risk also applies to children.
- tissue damage after Doxorubicin Hydrochloride Injection USP is given through a vein in your arm (intravenous administration). This might happen if Doxorubicin Hydrochloride Injection USP leaks out of your vein into the surrounding tissue and is called **extravasation**. You may get blisters or sores that require skin grafts. If it hurts, burns or stings in or around the vein into which the drug is being injected, tell the doctor or nurse IMMEDIATELY.
- severe **myelosuppression** including 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.

Your liver is important to processing Doxorubicin Hydrochloride Injection USP in your body. You should not use it if you have a severe liver disease.

What is Doxorubicin Hydrochloride for Injection USP used for?

Doxorubicin Hydrochloride for Injection USP is used:

- alone or with other anti-cancer medications to treat several different types of cancer.
- to treat superficial bladder tumors. For these tumors, Doxorubicin Hydrochloride for Injection USP is given directly in the bladder (intravesical administration).

How does Doxorubicin Hydrochloride for Injection USP work?

Doxorubicin Hydrochloride for Injection USP is a chemotherapy drug, often used in combination with other drugs, to kill fast dividing cells, such as cancer cells. This action can affect normal cells as well.

What are the ingredients in Doxorubicin Hydrochloride for Injection USP?

Medicinal ingredients: Doxorubicin hydrochloride

Non-medicinal ingredients: Lactose

Doxorubicin Hydrochloride for Injection USP comes in the following dosage forms:

Sterile powder for solution: 10 mg / vial, 50 mg / vial and 150 mg / vial

Do not use Doxorubicin Hydrochloride for Injection USP if:

- you are allergic to doxorubicin hydrochloride or to any other ingredient in this medicine or part of the container;
- you are allergic to other anthracycline or anthracenedione medicines such as epirubicin hydrochloride, daunorubicin hydrochloride, mitoxantrone or mitomycin C;
- you have persistent low blood cell count (myelosuppression);
- you have severe liver disease;
- you have severe heart disease;
- you had a recent heart attack;
- you have severe irregular heartbeat;
- you have history of severe heart disease;
- you have had treatment before with high doses of doxorubicin, daunorubicin, epirubicin, idarubicin and/or other anthracycline and anthracenedione medicines. Taking too much of these medicines may be harmful for your heart.

If Doxorubicin Hydrochloride for Injection USP is to be given directly into your bladder (intravesical administration), you should not use it if you have:

- blood in your urine;
- urinary tract infections;
- inflammation of the bladder.

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

- have low blood cell counts;
- have liver problems;
- have higher than normal levels of bilirubin in your blood;
- have or have a history of heart disease, recent heart attack or irregular heartbeat;
- are taking other medicines that affect your heart (including calcium channel blockers);

- have been previously treated with Doxorubicin Hydrochloride for Injection USP or other anti-cancer drugs, including anthracycline medicines;
- are taking trastuzumab or have had it within the last 7 months;
- have previously received radiation treatment to the chest.

Other warnings you should know about:

Vaccines: Receiving certain vaccines during your treatment might lead to serious or life-threatening infections. Tell your healthcare professional if you need a vaccine during your treatment. Certain vaccines should be avoided.

Pregnancy and breastfeeding – female patients:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take Doxorubicin Hydrochloride for Injection USP if you are pregnant. It may harm your unborn baby.
- If you are able to get pregnant:
 - avoid becoming pregnant while you are being treated with Doxorubicin Hydrochloride for Injection USP. Use effective birth control during treatment and for at least 6 months and 10 days after your last dose.
 - Tell your healthcare professional right away if you become pregnant, or think you may be pregnant during your treatment.
- Doxorubicin passes into breastmilk. You should not breastfeed during your treatment and for 10 days after your last dose. Talk to your healthcare professional about how to feed your baby during this time.

Pregnancy – male patients:

- Avoid fathering a child while you are being treated with Doxorubicin Hydrochloride for Injection USP.
- During your treatment, use effective birth control each time you have sex with a woman who is pregnant, may be pregnant or can get pregnant. Continue to use this birth control until 3 months and 10 days after your last dose.
- If, during your treatment with Doxorubicin Hydrochloride for Injection USP, your sexual partner becomes pregnant, or thinks she may be pregnant, tell your healthcare professional right away.

Fertility: Doxorubicin Hydrochloride for Injection USP may affect your ability to have a child during and after your treatment. If you want to have children, you may want to preserve your fertility.

- **Female patients:** You may stop getting a period and may not ovulate while you are receiving Doxorubicin Hydrochloride for Injection USP. Your menstrual cycle may return to normal after your last dose; however, you could also go into menopause early.
- **Male patients:** Doxorubicin Hydrochloride for Injection USP can affect your sperm. This may be permanent, but could return to normal after treatment is completed, even years later.

Check-ups and tests: You will have blood tests done regularly. These will be done before and during each treatment cycle. The results of these tests will tell your healthcare professional how Doxorubicin Hydrochloride for Injection USP is affecting your blood, liver and kidneys. You may also need to have tests to measure how well your heart is working. These tests might include MUGA and ECHO scans.

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 Doxorubicin Hydrochloride for Injection USP:

- medicines used to lower blood pressure including calcium channel blockers such as verapamil;
- medicines used to treat cancer including paclitaxel, 6-mercaptopurine, streptozocin, cyclophosphamide, actinomycin-D and sorafenib;
- medicines used to treat seizures such as phenobarbital and phenytoin;
- a medicine used to prevent rejection after an organ transplant called cyclosporine

Taking Doxorubicin Hydrochloride for Injection USP with other chemotherapy drugs that have a similar action may lead to more side effects especially low blood cell counts, gastrointestinal and heart problems.

How Doxorubicin Hydrochloride for Injection USP is given:

You will be given Doxorubicin Hydrochloride for Injection USP by a healthcare professional. It will be given in one of two ways:

Intravenous (IV) administration: Doxorubicin Hydrochloride for Injection USP is given through a vein in your arm.

- It usually takes about 3-10 minutes to inject Doxorubicin Hydrochloride for Injection USP. However, you may get other medicines before or after Doxorubicin Hydrochloride for Injection USP, so your entire treatment may last an hour or longer.
- Doxorubicin Hydrochloride for Injection USP will be given to you in treatment 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 Hydrochloride for Injection USP is usually given in treatment cycles of 21-days or 28-days. Your healthcare professional will tell you the schedule for your treatments and how often you will receive Doxorubicin Hydrochloride for Injection USP.
- Your healthcare professional will also decide for how long you will need Doxorubicin Hydrochloride Injection USP. It will depend on your medical condition, the medicines you receive, and how your body responds to these medicines.

Intravesical administration: Doxorubicin Hydrochloride for Injection USP is given through a catheter inserted through your urinary tract directly into your bladder.

- Doxorubicin Hydrochloride for Injection USP should generally be held in your bladder for 1-2 hours before urinating.
- Avoid drinking for 12 hours before your treatment.
- You will receive Doxorubicin Hydrochloride for Injection USP every 4-weeks.
- Your treatment may last more than 1 year. This will depend on how you respond and if you experience side effects.

Your healthcare professional will use specific techniques to prepare your dose. They will wear gloves, goggles and protective clothing.

If Doxorubicin Hydrochloride for Injection USP touches skin, the area should be washed with soap and water or sodium bicarbonate right away. If it gets into the eye, the eye should be flushed with a lot of water.

Usual dose: Your healthcare professional will decide the dose of Doxorubicin Hydrochloride for Injection USP that you will receive. It will be different for each patient and will depend on:

- your height, weight and age,
- the condition being treated,
- whether you have liver problems,
- whether you are taking other medicines
- if you will receive Doxorubicin Hydrochloride for Injection USP alone or with other anti-cancer medicines
- how often you will receive Doxorubicin Hydrochloride for Injection USP

Overdose:

Receiving a dose of Doxorubicin Hydrochloride for Injection USP that is too high can make side effects (like sores in the mouth) worse. It can also lower the number of white blood cells and platelets in the blood. If you receive too much Doxorubicin Hydrochloride for Injection USP over a long period of time, you are more likely to experience damage to the heart.

If you receive too much Doxorubicin Hydrochloride for Injection USP, your healthcare professional may give you platelet transfusions or other medicines. These medicines may be used to:

- treat infections or mouth sores
- help your body make white blood cells
- make your heart stronger and remove fluid from your body

If you think you, or a person you are caring for, have been given too much Doxorubicin Hydrochloride for Injection USP, 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, contact your healthcare professional as soon as possible to schedule your next treatment.

What are possible side effects from using Doxorubicin Hydrochloride for Injection USP?

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

- temporary hair loss
- nausea

- vomiting
- fatigue, or feeling tired
- mouth sores
- red coloration of your urine for 1 to 2 days after receiving Doxorubicin Hydrochloride for Injection USP.
- stomach pain
- eye redness, swelling or infection (pink eye)

Doxorubicin Hydrochloride for Injection USP can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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			
Anorexia: decreased appetite		√	
Diarrhea		√	
Infection: fever over 38°C , chills, sweating, nausea, vomiting, diarrhea, generally feeling unwell, 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		√	
Hemorrhage (bleeding)		√	
Heart problems: irregular heartbeat, chest pain, swelling of the ankles, shortness of breath		√	
Allergic skin reaction: pain at the site of the injection, rash, itch, redness		√	
RARE			
Colitis (inflammation of the bowel): diarrhea may have blood or pus, abdominal pain and cramping, pain in the rectum, fever, weight loss, fatigue		√	
Amenorrhea (loss of monthly periods): early menopause can occur leading to night sweats and hot flashes		√	
Dehydration (your body does not have sufficient water): dry mouth, excessive thirst, headache, loss of appetite, feeling tired and weak,		√	

lack of sweating, decreased blood pressure and urine, dark yellow urine			
Anaphylaxis (serious allergic reaction): difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat		√	
Thrombophlebitis (inflammation that causes a blood clot to form): swelling and redness along a vein which is extremely tender or painful when touched		√	
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath		√	
Phleboscclerosis (thickening and hardening of the wall of a vein): pain, blood clots, swelling of the legs or ankles		√	
Pericarditis and myocarditis (swelling of the sac around the heart or the heart muscle): sharp or piercing chest pain that can be more intense when breathing, shortness of breath, cough, rapid heartbeat		√	
Tumor-Lysis Syndrome (large number of cancer cells releasing their contents into the blood): feeling sick to your stomach, weak or tired, throwing up, diarrhea, muscle twitching or numbness, changes in urine, joint pain, confusion		√	
Mucositis (inflammation and ulcers of the lining of the digestive tract): mouth sores with pain, trouble swallowing, eating or talking, diarrhea, bloody stools, bloody vomit		√	

Hyperpigmentation of the oral mucosa: change in colour of the skin inside the mouth		√	
Shock (lack of blood flow): cool clammy skin, blue coloring of the lips or fingernails, fast heartbeat, weakness		√	
Chromonychia: changes in nail coloring, skin and nail changes, tingling sensation, urticaria (itchiness)		√	
Photosensitivity (sensitivity of the skin to UV rays in sunlight or other source): itchy, red skin when exposed to sunlight, tingling sensation		√	
Extravasation (leakage of Doxorubicin Hydrochloride for Injection USP from your vein to the tissue around it): blisters or sores, pain, tenderness, itchiness or burning at the site		√	
Cardiomyopathy (damage to the heart muscle): shortness of breath, swelling in the ankles, and fluid retention		√	
Myelosuppression (severe decrease in the number of white blood cells, red blood cells, and platelets): fever, serious infection, severe bleeding, fever or chills with shivering		√	
Blood cancers: swelling of the neck or armpits, bone pain, night sweats, feeling weak, quickly losing a lot of weight, bleeding or bruising more easily, fever or chills		√	

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/adverse-reaction-reporting.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:

Your healthcare professional will store Doxorubicin Hydrochloride for Injection USP between 15°C and 25°C. They will protect it from light.

If you want more information about Doxorubicin Hydrochloride for Injection USP:

- 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 <https://www.pfizer.ca/>, or by calling 1-800-463-6001.

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