

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrZINECARD®

#### Dexrazoxane for injection

Read this carefully before you start taking **Zinecard** and each time you get an injection. 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 **Zinecard**.

#### Serious Warnings and Precautions

Zinecard should only be given to you by healthcare professionals experienced in the use of cancer chemotherapy drugs.

- **Myelosuppression** (lower bone marrow action): Zinecard can contribute to lower bone marrow action. This lowers the blood cell count in your body and can make your immune system more weak. This can make it easier for you to get sick or have an infection.
- **Pregnancy and breastfeeding:** Zinecard can harm your unborn baby.
  - Avoid getting pregnant while on Zinecard. Use effective birth control.
  - Tell your healthcare professional right away if you think you are pregnant while on Zinecard.
  - If you are pregnant or plan to become pregnant, there are specific risks you should discuss with your healthcare professional.
  - It is not known if Zinecard passes into your breast milk. You should not breast feed your baby if you are being treated with Zinecard.
- **Liver and Kidney problems:** Your healthcare professional will adjust your dose of Zinecard if you have liver or kidney problems. Your blood cells and liver and kidney function will need to be tested often.

#### What is Zinecard used for?

Zinecard is used in adults to reduce or prevent heart damage caused by:

- Treatment with doxorubicin in women with breast cancer that has spread to other parts of the body.

Zinecard is not an anticancer drug.

#### How does Zinecard work?

Zinecard enters cell membranes to protect the heart muscle from heart damage caused by other anti-cancer medicines.

#### What are the ingredients in Zinecard?

Medicinal ingredient: Dexrazoxane

Non-medicinal ingredient: Hydrochloric acid

#### Zinecard comes in the following dosage forms:

Zinecard is a lyophilized powder for injection. It is available in vials of 250 mg or 500 mg.

**Do not use Zinecard if:**

- you are allergic to dexrazoxane, any other ingredients of Zinecard, or components of the container.
- you are under 18 years of age.
- your cancer treatment does not include doxorubicin.

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

- Have liver problems
- Have kidney problems
- Have heart problems
- Are 65 years of age or older
- Are pregnant, think you are pregnant or plan to become pregnant
- Are breastfeeding

**Other warnings you should know about:**

Zinecard may increase the risk of having:

- Cancer of the blood (**Acute Myeloid Leukaemia**)
- Blood clots in the vein or artery (**thromboembolism**)

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

**Check-ups and Testing:** You will have regular visits with your healthcare professional, before, during and at the end of your treatment. They will do:

- Blood and urine tests to check your liver, kidney and blood health
- Imaging tests to check your heart health

**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 Zinecard:**

- Medicines used to treat different cancers such as fluorouracil and cyclophosphamide.

**How to take Zinecard:**

- Your healthcare professional will mix Zinecard into a solution. They will inject the solution into a vein by rapid intravenous infusion. You will receive this injection in a clinic or hospital setting.
- Zinecard is given to you between 15 to 30 minutes before the treatment with an anti-cancer drug called doxorubicin.

- Your healthcare professional will follow proper safe handling directions. Gloves should be worn.

**Usual dose:**

- **Adults:** Your healthcare professional will choose the dose of Zinecard that is right for you.

Your healthcare professional may interrupt or stop your treatment or reduce your dose. This may happen if you:

- experience side effects, or
- your disease has gotten worse.

**Overdose:**

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

**What are possible side effects from using Zinecard?**

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

Side effects may include:

- hair loss
- nausea, vomiting, diarrhea
- tiredness
- decreased appetite
- mouth sores
- fever, infection
- redness of the blood vessels
- difficulty swallowing, burning sensation of the esophagus
- itching
- bleeding
- tissue swelling, redness and pain at the injection site
- skin reaction in areas where other agents were used

Zinecard might cause abnormal blood test results. Your healthcare professional will treat you accordingly.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON</b>			
<b>Myelosuppression</b> (a large decrease in the production of		√	

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	
blood cells and platelets by the bone marrow): bleeding, bruising, chills, fatigue, fever, infections, weakness, shortness of breath or other signs of infection			
<b>Neurotoxicity</b> (damage to the nervous system): agitation, blurred vision, confusion, convulsions, difficulty speaking, dizziness, hallucinations, headache, impaired thinking, loss of control of body movements, memory loss, mental status changes, nervousness, numbness and tingling, vision loss, muscle weakness, seizures		√	
<b>COMMON</b>			
<b>Congestive Heart Failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise		√	
<b>Phlebitis</b> (swelling of a vein): pain, tenderness, redness or swelling		√	
<b>Myelodysplastic Syndrome or Acute Myeloid Leukaemia</b> (a group of diseases in which the body produces large numbers of abnormal blood cells): Fever, infection, bruising or bleeding easily, breathlessness, blood in urine or stool		√	
<b>UNKNOWN</b>			
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, loss of consciousness, swelling of the face, lips, tongue or throat.		√	

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	
<b>Thromboembolism</b> (blood clot in a vein or artery): pain or tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness		√	

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:

Your healthcare professional will store, handle and dispose of Zinecard.

- **Dry powder:** Store vials at 15-30°C.
- **Reconstituted solution:** Store 30 minutes at room temperature or a maximum of 3 hours at 2-8°C.
- **Reconstituted and diluted solution:** Store 1 hour at room temperature or a maximum of 4 hours at 2-8°C.

Keep out of reach and sight of children.

### If you want more information about Zinecard:

- 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](http://www.pfizer.ca), or by calling 1-800-463-6001.

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