

PART III: CONSUMER INFORMATION

**ZINECARD
Dexrazoxane for Injection**

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

ABOUT THIS MEDICATION

What the medication is used for:

ZINECARD is used to reduce or prevent the incidence and severity of the heart damage (cardiotoxicity) caused by doxorubicin in women with metastatic breast cancer.

What it does:

ZINECARD penetrates cell membranes to protect the heart muscle from anthracycline-induced cardiotoxicity by interfering with iron-mediated free radical generation.

When it should not be used:

ZINECARD should not be used in patients who are allergic to dexrazoxane or components of the container of ZINECARD.

ZINECARD is not indicated for use in patients under 18 years of age.

You should not receive ZINECARD if your cancer treatment does not include doxorubicin.

ZINECARD is not an anticancer drug.

What the medicinal ingredient is:

Dexrazoxane.

What the important nonmedicinal ingredients are:

There are no other ingredients.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **If you are prescribed ZINECARD, it will only be given to you by doctors or nurses experienced in giving chemotherapy.**
- **ZINECARD can add to the bone marrow lowering effects of chemotherapy. This can weaken your immune system, making it easier for you to get sick from being around others who are ill.**
- **Using ZINECARD while you are pregnant can harm your unborn baby, so you should avoid becoming pregnant and use effective birth control. If you think you have become pregnant while using this medicine, tell your doctor right away.**
- **To be sure this medication is not causing harmful effects, your blood cells and liver and kidney function will need to be tested often. Do not miss any follow up visits to your doctor for blood or urine tests.**

ZINECARD may increase the risk of having:

- An infection (due to low white blood cell count)
- Leukaemia (cancer of the blood)
- Blood clots
- An allergic reaction (hives; difficulty breathing; swelling of your face, lips, tongue, or throat)

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

- Have liver problems
- Have kidney problems
- Have heart problems
- Are pregnant or plan to become pregnant
- Are breastfeeding

INTERACTIONS WITH THIS MEDICATION

Some cancer medications may be less effective if they are used with ZINECARD. Tell your doctor if your chemotherapy medications include:

- fluorouracil
- cyclophosphamide

This list is not complete and other drugs may interact with dexrazoxane. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor.

PROPER USE OF THIS MEDICATION

ZINECARD is injected in to a vein through an IV. You will receive this injection in a clinic or hospital setting.

ZINECARD is to be given to you as a rapid intravenous infusion, between 15 to 30 minutes before the treatment with doxorubicin.

Usual dose: the recommended dosage ratio for ZINECARD and doxorubicin is 10:1 or 500 mg/m² ZINECARD given before the 50 mg/m² doxorubicin.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects (affecting more than 10 out of every 100 people) include:

- low blood cell count
- hair loss
- nausea, vomiting, diarrhea
- tiredness
- anorexia
- mouth sores
- fever, infection
- damage to nerve tissue
- pain at the injection site

Common side effects (affecting between 1 and 10 of every 100 people) include:

- redness of the blood vessels
- difficulty swallowing
- swelling of a vein
- itching
- burning sensation of the esophagus
- bleeding
- tissue swelling, redness and pain at the injection site
- skin reaction in the areas previously exposed to other agents
- heart failure

If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Low concentration of granulocytes in the blood - a type of white blood cells		√	

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

HOW TO STORE IT

ZINECARD lyophilized powder for injection should be stored at controlled room temperature, 15-30°C. The reconstituted solution in Sterile Water for Injection is stable for 30 minutes at room temperature or a maximum of 3 hours under refrigeration, 2-8°C. The reconstituted solution when further diluted with Lactated Ringer's Injection is stable for 1 hour at room temperature or a maximum of 4 hours under refrigeration, 2-8°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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 www.healthcanada.gc.ca/medeffect
- 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 0701D
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 www.healthcanada.gc.ca/medeffect.

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 Pfizer Canada Inc. Medical Information at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

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