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Pharmaceutical Products

April 11, 2019

Subject: A limited quantity of US labelled Pfizer PrZINECARD® (dexrazoxane for injection) in the 250 mg format will be made available for Canadian patients



Dear Customer,


Pfizer Canada, wishes to provide an update regarding the drug shortage situation for PrZINECARD® (dexrazoxane for injection), in the 250 mg format.

In order to mitigate the impact of the current market shortage, a **limited quantity** of US-labeled Pfizer ZINECARD (lot **ADA047B with expiry date 04/30/2021**) will be made available to the Canadian market. Ordering restrictions will apply and product will be distributed on an emergency use basis only.

The US-labelled ZINECARD is identical to the Canadian-labelled product, in terms of the actual drug product content and container closure. The differences relate to the language (i.e. English only) and information provided on both the vial label and carton. An example of the vial labels and cartons from both the US and Canada are provided below.

Please note that given the criticality of this product, we will continue to closely monitor the selling patterns during this period and we will adjust our allocation strategy as necessary. **We are strongly recommending that clinicians make every effort to reserve supplies for critical care uses only and redistribute stock between sites whenever possible prior to reordering.**

Please refer to the table below for some additional information and the availability dates.

NDC	NAME	DESCRIPTION	FORMAT	UPC	ALLOCATION	BARCODE	ESTIMATED AVAILABILITY (MM/DD/YYYY)
0013-8717-62	ZINECARD (US labeled)	Sterile, Powder for Solution, 250 mg	vial, 1 x 25 mL	300138 717628	Emergency Use		Main Pfizer Warehouse: 04/11/2019 CPDN Ontario: 04/12/2019 CPDN Alberta: 04/16/2019 CPDN British Columbia: 04/16/2019

Pfizer understands and regrets the inconvenience that this situation may cause for patients and clinicians. All efforts are being made to minimize the impact of this shortage on the market.

Please note that page 2 has a visual representation of both labels for your convenience.

Please note that this information is reflected in our weekly **Product Availability Report (PAR)**. For the latest updates on product availability, please refer to our Product Availability Report on www.pfizerinjectables.ca.

For all inquiries including, medical information, allocations and general information related to this product please contact 1-800-387-4974.

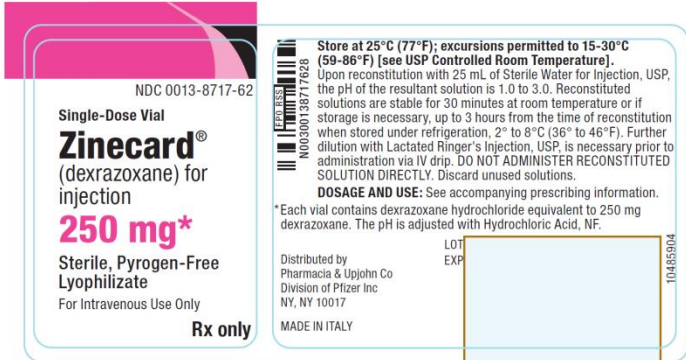
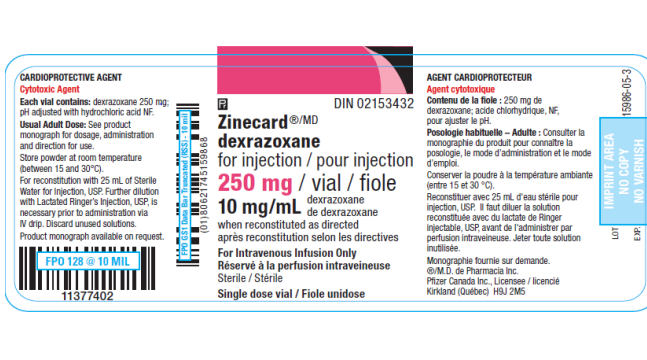


Sincerely,

Denis Tremblay
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 PFIZER CANADA INC.
 DT/ds



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US vial label	Canadian vial label
 <p>US vial label</p> <p>Single-Dose Vial Zinecard® (dexrazoxane) for injection 250 mg* Sterile, Pyrogen-Free Lyophilizate For Intravenous Use Only Rx only</p> <p>Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Upon reconstitution with 25 mL of Sterile Water for Injection, USP, the pH of the resultant solution is 1.0 to 3.0. Reconstituted solutions are stable for 30 minutes at room temperature or if storage is necessary, up to 3 hours from the time of reconstitution when stored under refrigeration, 2° to 8°C (36° to 46°F). Further dilution with Lactated Ringer's Injection, USP, is necessary prior to administration via IV drip. DO NOT ADMINISTER RECONSTITUTED SOLUTION DIRECTLY. Discard unused solutions.</p> <p>DOSAGE AND USE: See accompanying prescribing information.</p> <p>*Each vial contains dexrazoxane hydrochloride equivalent to 250 mg dexrazoxane. The pH is adjusted with Hydrochloric Acid, NF.</p> <p>Distributed by Pharmacia & Upjohn Co Division of Pfizer Inc NY, NY 10017</p> <p>MADE IN ITALY</p>	 <p>Canadian vial label</p> <p>Zinecard®/MD dexrazoxane for injection / pour injection 250 mg / vial / fiole 10 mg/mL dexrazoxane when reconstituted as directed après reconstitution selon les directives For Intravenous Infusion Only Sterile / Stérile Single dose vial / Fiole unidose</p> <p>AGENT CARDIOPROTECTEUR Agent cytotoxique Contenu de la fiole : 250 mg de dexrazoxane, sels chlorhydrique, NF, pour ajuster le pH. Posologie habituelle – Adulte : Consulter la monographie du produit pour connaître la posologie, le mode d'administration et le mode d'emploi. Conserver la poudre à la température ambiante (entre 15 et 30 °C). Reconstituer avec 25 mL d'eau stérile pour injection, USP. Il faut diluer la solution reconstituée avec du lactate de Ringer injectable, USP, avant de l'administrer par perfusion intraveineuse. Jeter toute solution inutilisée. Monographie fournie sur demande. ©M.D. de Pharmacia Inc. Pfizer Canada Inc., Licencier / licensee Kirkland (Québec) H9J 2M5</p>
English only	English and French
NDC 0013-8717-62	DIN 02153432
Does not indicate concentration (10 mg/mL) following reconstitution	Indicates concentration (10 mg/mL) following reconstitution
Not indicated as "Cytotoxic agent"	Indicated as "Cytotoxic agent"
Stated "pH of the resultant solution is 1.0 to 3.0"	pH statement missing from vial label but present on the Canadian carton.
Stability information regarding the reconstituted product both at room temperature and refrigerated are indicated.	Stability information regarding the reconstituted product not indicated. The stability information regarding the reconstituted product, refrigerated, is indicated on the Canadian carton. Alternatively, complete stability information, identical to the US vial label, is detailed in the Product Monograph.
Statement "Do not administer reconstituted solution directly" is present.	Statement "Do not administer reconstituted solution directly" is not present on Canadian vial, but present on the Canadian carton.
Statement for Dosage and Use is "See accompanying prescribing information".	Statement for usual adult dose is "See Product Monograph for dosage, administration and direction for use."
US carton	Canadian carton
 <p>US carton</p> <p>Single-Dose Vial Zinecard® (dexrazoxane) for injection 250 mg* Sterile, Pyrogen-Free Lyophilizate For Intravenous Use Only Rx only</p> <p>Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Upon reconstitution with 25 mL of Sterile Water for Injection, USP, the pH of the resultant solution is 1.0 to 3.0. Reconstituted solutions are stable for 30 minutes at room temperature or if storage is necessary, up to 3 hours from the time of reconstitution when stored under refrigeration, 2° to 8°C (36° to 46°F). Further dilution with Lactated Ringer's Injection, USP, is necessary prior to administration via IV drip. DO NOT ADMINISTER RECONSTITUTED SOLUTION DIRECTLY. Discard unused solutions.</p> <p>DOSAGE AND USE: See accompanying prescribing information.</p> <p>*Each vial contains dexrazoxane hydrochloride equivalent to 250 mg dexrazoxane. The pH is adjusted with Hydrochloric Acid, NF.</p> <p>Distributed by Pharmacia & Upjohn Co Division of Pfizer Inc NY, NY 10017</p> <p>MADE IN ITALY</p>	 <p>Canadian carton</p> <p>Zinecard®/MD dexrazoxane pour injection 250 mg / fiole 10 mg/mL de dexrazoxane</p> <p>AGENT CARDIOPROTECTEUR Agent cytotoxique Contenu de la fiole : 250 mg de dexrazoxane, sels chlorhydrique, NF, pour ajuster le pH. Posologie habituelle – Adulte : Consulter la monographie du produit pour connaître la posologie, le mode d'administration et le mode d'emploi. Conserver la poudre à la température ambiante (entre 15 et 30 °C). Après la reconstitution du produit avec 25 mL d'eau stérile pour injection, USP, le pH de la solution sera de 1,0 à 3,0. La solution reconstituée est stable pendant 3 heures si elle est conservée au réfrigérateur à une température de 2 à 8 °C. Il faut diluer la solution reconstituée avec du lactate de Ringer injectable, USP, avant de l'administrer par perfusion intraveineuse. NE PAS ADMINISTRER DIRECTEMENT LA SOLUTION RECONSTITUÉE. Jeter toute solution inutilisée. Monographie fournie sur demande. ©M.D. de Pharmacia Inc. Pfizer Canada Inc., Licencier / licensee Kirkland (Québec) H9J 2M5 http://www.pfizer.ca 1-800-463-0021</p>
English only	English and French
NDC 0013-8717-62	DIN 02153432
Does not indicate concentration (10 mg/mL) following reconstitution	Indicates concentration (10 mg/mL) following reconstitution
Not indicated as "Cytotoxic agent"	Indicated as "Cytotoxic agent"
Stated "pH of the resultant solution is 1.0 to 3.0"	pH statement missing from vial label but present on the Canadian carton.
Stability information regarding the reconstituted product both at room temperature and refrigerated are indicated.	Only the refrigerated stability information of the reconstituted product is indicated. Alternatively, complete stability information, identical to the US vial label, is detailed in the Product Monograph.
Does not specifically indicate "without diluent".	Statement "without diluent" is present.
Statement for Dosage and Use is "See accompanying prescribing information".	Statement for usual adult dose is "See Product Monograph for dosage, administration and direction for use."
Prescribing information included in the carton.	There is no insert in the Canadian carton. Healthcare professionals are encouraged to consult the www.pfizer.ca site.