Bristol Myers Squibb®

Importation of US-labelled ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) due to the current Shortage of Canadian-authorized ABRAXANE® for Injectable Suspension (paclitaxel powder for injectable suspension nanoparticle, albumin-bound paclitaxel)

Bristol-Myers Squibb Canada
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Montreal, QC
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June 04, 2026

Dear Healthcare professionals who prescribe, dispense or administer ABRAXANE® for Injectable Suspension

There is a current critical shortage of ABRAXANE® for Injectable Suspension in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Bristol-Myers Squibb's US-labelled ABRAXANE® for Injectable Suspension, with English-only labels, by Bristol-Myers Squibb Canada.

Health Canada has accepted the addition of Bristol-Myers Squibb's product to the **List of drugs for exceptional importation and sale** [https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html].

In Canada, ABRAXANE® for Injectable Suspension is indicated for the treatment of metastatic breast cancer and the first-line treatment of metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

The US-labelled product has the **same active ingredient, strength, dosage form, volume, product formulation, and route of administration** as the Canadian-authorized product. However, the **product labelling differs in the following ways**:

- The US product has an additional indication for non-small cell lung cancer that is not approved for the Canadian product.
- The Canadian product has more detailed dose-adjustment guidance and broader warnings/precautions.
- The US product has additional hypersensitivity administration guidance.

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Quality Unit Lead

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The US-labelled product should be used in the same manner as the Canadian-authorized product. Healthcare professionals should refer to the Canadian Product Monograph for ABRAXANE® for Injectable Suspension, 100 mg/vial (DIN 02281066) available in English and French on the Health Canada **Drug Product Database** [https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html]. The database contains information on the appropriate use of the product, including the:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- dosage and administration
- storage conditions
- handling instructions

Information on the imported product

Brand name	Dosage form, strength, and route of administration	Product packaging	Country of authorization and identifying code	Foreign authorization holder	Importer in Canada
ABRAXANE® for Injectable Suspension	Powder for suspension, 100 mg paclitaxel per vial, For intravenous use only	Single-dose vial, individually packaged in a carton	USA NDC: 68817-134-50	Bristol-Myers Squibb Company, USA	Bristol-Myers Squibb Canada

Additional information about US-labelled ABRAXANE® for Injectable Suspension for healthcare professionals is available for reference in English only at https://www.bms.com/patient-and-caregivers/our-medicines.html.

Images of the US-labelled product can be found in the Appendix below.

Healthcare professionals are advised that aspects of the vial and carton labels and packaging of the US-labelled product differ from the Canadian-authorized ABRAXANE® for Injectable Suspension. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

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The key attributes from the Canadian vial and carton labels which are **absent** from the US vial and carton labels, include:

- Drug Identification Number (DIN)
- Name and address of the Canadian DIN holder and Importer
- Corresponding text in French

All shipments of the US-labelled ABRAXANE® for Injectable Suspension will include a copy of this current risk communication letter from Bristol-Myers Squibb Canada (English and French).

This Canadian barcode can be used to scan in medication management systems in Canada.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of ABRAXANE® for Injectable Suspension should be reported to Bristol-Myers Squibb Canada, or to **Health Canada** at [https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html] or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about US-labelled ABRAXANE® for Injectable Suspension, please contact Bristol-Myers Squibb Canada at **1-866-463-6267**.

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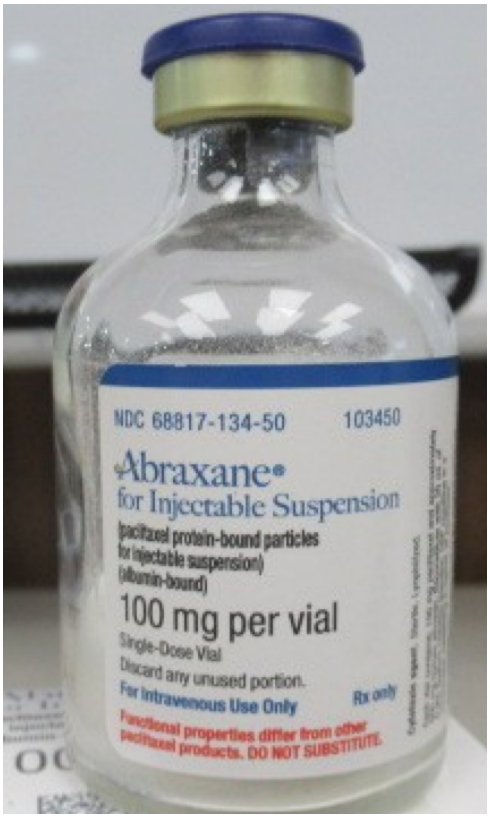
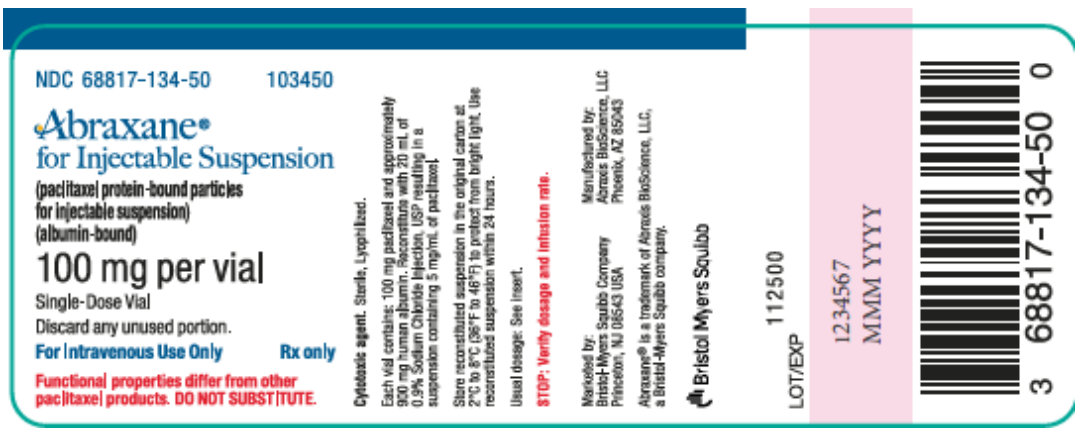
Appendix

US-labelled ABRAXANE® for Injectable Suspension vial:



US-labelled ABRAXANE® for Injectable Suspension vial label:



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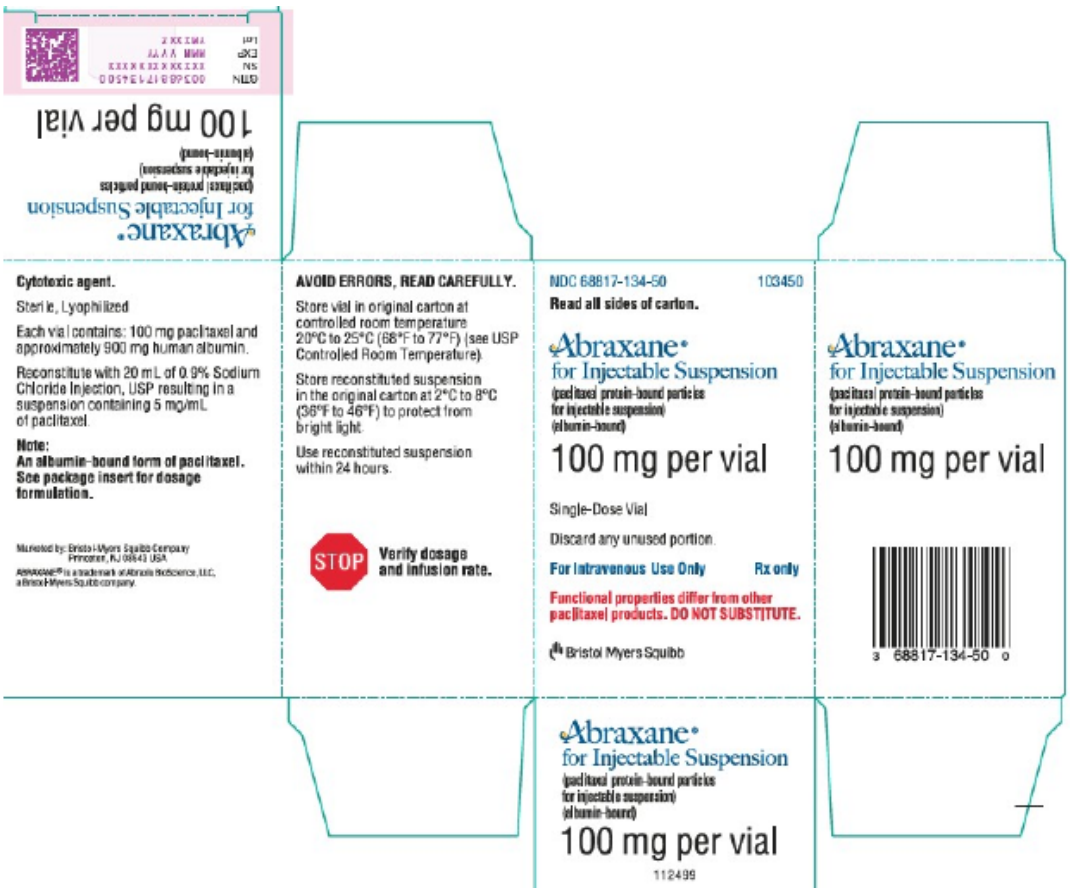
US-labelled ABRAXANE® for Injectable Suspension carton label:



Sincerely,
Dominique Lavallée

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