



2021/06/28

Exceptional importation of limited quantity of Pfizer's US-Labelled DEPO-PROVERA Contraceptive Injection (CI) (medroxyprogesterone acetate injectable suspension) 150 mg/mL prefilled syringe to alleviate Canadian drug shortage

Dear Healthcare Professionals,

Key Messages

- Pfizer is experiencing a shortage of DEPO-PROVERA (medroxyprogesterone acetate injectable suspension) 150 mg/mL vials on the Canadian market.
- Given the medical necessity of this product in Canada and to help mitigate the current shortage, Health Canada has added Pfizer's US-labelled DEPO-PROVERA CI 150mg/mL prefilled syringes to the List of Drugs for Exceptional Importation and Sale.
- The US-labelled DEPO-PROVERA CI 150 mg/mL is available in 1 mL prefilled glass syringes whereas the Canadian-approved DEPO-PROVERA 150 mg/mL is available in 1 mL glass vials.
- **The US-labelled DEPO-PROVERA CI 150 mg/mL prefilled syringe is indicated only for the prevention of pregnancy and is not indicated for the treatment of endometriosis.**
- Healthcare professionals should refer to the **US Prescribing Information** for DEPO-PROVERA CI 150 mg/mL prefilled syringe available at <http://labeling.pfizer.com/ShowLabeling.aspx?id=522> for **Indications and Dosage and Administration**.
- However, for **Contraindications, Serious Warnings and Precautions Box, and Warnings and Precautions**, healthcare professionals should refer to the **Canadian Product Monograph** for DEPO-PROVERA 150 mg/mL. The Canadian Product Monograph for DEPO-PROVERA 150 mg/mL is available on the Health Canada Drug Product Database: <https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=19667>.
- The US-labelled DEPO-PROVERA CI 150 mg/mL prefilled syringe is labelled in English only. The French-translated text of the US prefilled syringe inner and outer labels and a link to the French-translated US Prescribing Information are included below.

Issue

Pfizer is facing a DEPO-PROVERA (medroxyprogesterone acetate injectable suspension) 150 mg/mL vials shortage on the Canadian market. Given the medical necessity of this product in Canada and to help mitigate the current shortage, Health Canada has added Pfizer's US-labelled DEPO-PROVERA CI 150 mg/mL prefilled syringes to the List of Drugs for Exceptional Importation and Sale.

Imported product

Product Name	Strength and Format	Lot Number	Expiry
DEPO-PROVERA CI (medroxyprogesterone acetate injectable suspension)	150 mg/mL prefilled syringes	EY6781	30-04-2025
		EY6782	31-08-2025
		FF6007	30-06-2025

Information for healthcare professionals

DEPO-PROVERA (medroxyprogesterone acetate injectable suspension) is a long-acting progestational steroid (progestogen) derived from a natural source (soybeans).

In Canada, DEPO-PROVERA is indicated for:

- conception control (prevention of pregnancy)
- treatment of endometriosis

The Canadian-approved DEPO-PROVERA 150 mg/mL is available in 1 mL glass vials. Although the Canadian DEPO-PROVERA 50 mg/mL strength formulation has been discontinued, there may be some product still on the Canadian market as the last lot sold expires on January 31, 2022.

The US-labelled DEPO-PROVERA CI 150mg/mL and the Canadian-labelled DEPO-PROVERA have the same active ingredients and route of administration, but they have the following differences:

	Indication	Packaging
US-labelled DEPO-PROVERA CI 150mg/mL	Indicated only for the prevention of pregnancy and is not indicated for the treatment of endometriosis and therefore should not be used in this indication.	1 mL prefilled syringes
Canadian-labelled DEPO-PROVERA 150 mg/mL	Indicated for: <ul style="list-style-type: none">• conception control (prevention of pregnancy)• treatment of endometriosis	1 mL glass vials

Healthcare professionals should refer to the **US Prescribing Information** for US-labelled DEPO-PROVERA CI 150 mg/mL prefilled syringe available at <http://labeling.pfizer.com/ShowLabeling.aspx?id=522> for **Indications and Dosage and Administration**. This communication in both French and English, as well as the French-translated US Prescribing Information are available at <https://www.pfizer.ca/depo-provera-medroxyprogesterone-acetate-injectable-suspension-usp>.

However, for **Contraindications, Serious Warnings and Precautions Box, and Warnings and Precautions**, healthcare professionals should refer to the **Canadian Product Monograph** for DEPO-PROVERA 150 mg/mL. The Canadian Product Monograph for DEPO-PROVERA 150 mg/mL is available on the Health Canada Drug Product Database: <https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=19667>.

The US-labelled DEPO-PROVERA CI 150 mg/mL prefilled syringe does not have a Drug Identification Number (DIN) and the barcode may not scan in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered. Proper selection of the intended product must be confirmed to avoid confusion with other products. To facilitate access, the provinces and territories have assigned a Product Identification Number (PIN) to this product which should be used when submitting claims. Consult each provincial or territorial temporary benefit listing status notice.

Report health or safety concerns

Adverse drug reactions associated with the use of DEPO-PROVERA 150 mg/mL should be reported to Pfizer Canada ULC by calling 1-866-723-7111 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.

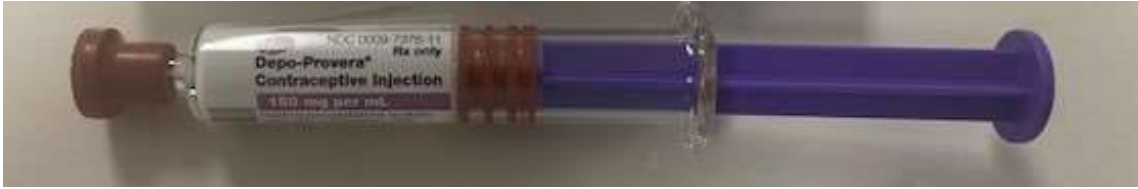
For Medical Inquiries, please contact Medical Information at 1-800-463-6001 or you can also access Medical Information via www.pfizermedinfo.ca. For Allocation Inquiries please contact our Allocation Specialist via email: allocation@pfizer.com, or by phone at 1-888-999-8750. For General Inquiries: Please contact our Customer Service Group at 1-800-387-4974.

Sincerely,



Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

Image of the US prefilled syringe



US prefilled syringe inner label

French-translation



Rx seulement

Depo-Provera^{MD}
 contraceptif injectable
 150 mg/mL
 suspension injectable d'acétate de
 médroxyprogestérone, USP
 Réservé à la voie intramusculaire
 Seringue unidose de 1 mL
 Agiter vigoureusement avant l'usage
 Pfizer Inc., NY, NY 10017

US prefilled syringe outer carton labels

French-translations



Depo-Provera® Contraceptive Injection NDC 0009-7376-11
 (medroxyprogesterone acetate) injectable suspension, USP

150 mg per mL

Intramuscular use only **Rx only**
 Single Use Syringe

1 mL Prefilled Syringe

NDC 0009-7376-11
 Depo-Provera^{MD}
 contraceptif injectable
 suspension injectable d'acétate de
 médroxyprogestérone, USP

150 mg/mL Rx


seulement

Réservé à la voie intramusculaire
 Seringue unidose

Seringue préremplie de 1 mL

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Shake vigorously before use with protective cap in place.
www.Depo-Provera.com

DOSAGE AND USE:
 See accompanying prescribing information.
 Each mL contains medroxyprogesterone acetate 150 mg.
 Also contains polyethylene glycol 3350, 28.5 mg; polysorbate 80, 2.37 mg; sodium chloride, 8.56 mg; and added as preservatives, methylparaben, 1.35 mg; propylparaben, 0.147 mg. When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.



N 3 0009-7376-11 9

Conserver à une température ambiante contrôlée entre 20 et 25 °C (68 à 77 °F) [voir USP]. Agiter vigoureusement la seringue munie de son capuchon de protection avant l'usage.

www.Depo-Provera.com

POSOLOGIE ET UTILISATION :
 Voir les renseignements posologiques ci-joints.
 Chaque mL contient 150 mg d'acétate de médroxyprogestérone, en plus de 28,5 mg de polyéthylèneglycol 3350, 2,37 mg de polysorbate 80, 8,56 mg de chlorure de sodium, ainsi que 1,35 mg de parahydroxybenzoate de méthyle et 0,147 mg de parahydroxybenzoate de propyle (comme agents de conservation). Au besoin, de l'hydroxyde de sodium ou de l'acide chlorhydrique peut être ajouté pour ajuster le pH.

Syringe Preparation:

1. Shake vigorously before use with protective cap in place.
2. Hold syringe upright and remove protective cap.
3. Attach the needle* to the syringe barrel.
4. Remove the safety shield from the needle.
5. Administer dose.

*Terumo® and SurGuard® are registered trademarks of Terumo

Terumo® SurGuard® Needle Activation:

1. After completing the injection, remove the needle from the skin and activate the safety shield.
2. Position shield about 40°- 45°. With a firm quick motion, press down against a flat surface until a click is heard or felt.
3. Discard appropriately.



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Préparation de la seringue :

1. Agiter vigoureusement la seringue munie de son capuchon protecteur avant l'usage.
2. Tenir la seringue à la verticale et retirer le capuchon de protection.
3. Fixer l'aiguille* au corps de la seringue.
4. Retirer le protège-aiguille.
5. Administer la dose.

* Terumo® et SurGuard® sont des marques déposées de Terumo.

Activation du protège-aiguille

	<p>Terumo® SurGuard® :</p> <ol style="list-style-type: none"> 1. Après l'injection, retirer l'aiguille du point d'injection et activer le protège-aiguille. 2. Placer le protège-aiguille à un angle de 40 à 45°. D'un geste rapide, exercer une pression contre une surface plane jusqu'à l'obtention d'un clic sonore ou tactile. 3. Jeter de façon appropriée.
	<p>Depo-Provera^{MD} contraceptif injectable suspension injectable d'acétate de médroxyprogestérone, USP</p> <p>150 mg/mL</p> <p>Seringue préremplie de 1 mL</p>
	<p>Depo-Provera^{MD} contraceptif injectable suspension injectable d'acétate de médroxyprogestérone, USP</p> <p>150 mg/mL</p> <p>Réservé à la voie intramusculaire Seringue unidose</p> <p>Seringue préremplie de 1 mL</p> <p>Distribué par Pharmacia & Upjohn Compagny Division de Pfizer Inc., NY, NY 10017</p>