

Importation of UK-labelled APO-go PEN (Apomorphine Hydrochloride Solution for Injection) due to the current shortage of Apomorphine Hydrochloride Injection in Canada

Accuristix
100 Vaughan Valley Boulevard,
Vaughan, Ontario, Canada
L4H 3C5

08 January 2024,

Dear Parkinson organization,

There is a critical shortage of Movapo (Apomorphine Hydrochloride Injection, 10 mg / mL) as this product is no longer marketed (i.e., discontinued) in Canada. To help mitigate the acute shortage and facilitate a transition period, Health Canada has permitted the exceptional, temporary importation and sale of United Kingdom (UK)-labelled APO-go PEN (Apomorphine Hydrochloride Solution for Injection), with English only labels, by Accuristix.

Health Canada has accepted the addition of this drug product to the [List of drugs for exceptional importation and sale \(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>\).](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html)

In Canada, Movapo (Apomorphine Hydrochloride Injection, 10 mg/mL) was a prescription drug product indicated for the acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) in patients with advanced Parkinson’s disease.

The UK-labelled product is supplied as a pre-filled pen with a total of 30 mg of apomorphine hydrochloride in 3 mL volume (30 mg / 3 mL) per cartridge (pen), with a dosage concentration of 10 mg/mL. The “cartridge” terminology used for the UK-labelled product is equivalent to the Canadian “PEN” terminology used for Movapo.

The UK-labelled product has the **same active ingredient (apomorphine hydrochloride), strength (10 mg/mL), dosage form (solution), packaging (pre-filled pen), and route of administration (subcutaneous) as Movapo**. Both the UK-labelled product and Movapo **contain sodium bisulfite (E222), used as an excipient antioxidant**.

However, the UK-labelled product **differs with respect to the brand name** (the UK-labelled product is named “APO-go PEN” while the Canadian product is named “Movapo”).

The UK-labelled product can be used in the same manner as Movapo. Healthcare professionals should refer to the Canadian Product Monograph for Movapo available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on appropriate use including the indications, contraindications, warnings and precautions, adverse reactions, drug interactions, dosage and administration, storage conditions, and handling instructions.

In addition to the difference in brand name, pharmacists are advised/reminded to inform patients of the following:

- The UK-labelled drug product should be used in the same manner as Movapo.
- Patients should **NOT** take another dose of Apomorphine Hydrochloride Injection **sooner than 2 hours** after the last dose.

Table 1: Information on the imported product

Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
APO-go PEN	Solution, 10 mg/mL apomorphine hydrochloride (30 mg / 3 mL), Subcutaneous injection	Solution for Injection Available in boxes of 5 cartridges (pens) of 3 mL. Each 3 mL cartridge contains 30 mg apomorphine hydrochloride.	United Kingdom, PL 04483/0073	Britannia Pharmaceuticals Ltd., UK Laboratoire Aguetant (France) is the manufacturer of the product. Aguetant can be contacted at injectables@aguettant.ca	Accuristix 100 Vaughan Valley Boulevard, Vaughan, Ontario, Canada, L4H 3C5

The UK-labelled product has a shelf-life of 24 months and should be **stored as per the labelled storage instructions for Movapo**. The storage instructions on the box label for Movapo are as follows:

- **Unopened PEN:** Store at 25°C (storage between 15°C to 30°C is acceptable). Keep the PEN in the original box to protect from light.
- **Opened PEN:** Store at room temperature (15°C to 30°C). Throw away the PEN 48 hours after opening.

Information about the UK-labelled product for reference by healthcare professionals can be found in the English Summary of Product Characteristics at:

https://aguettant.ca/fileadmin/aguettant_canada/SPC_APO-go.pdf

The UK SmPC included in the package is for both the UK product (marketing authorization number PL 04483/0073) and Malta product (marketing authorization number MA830/00302) countries

.and UK package leaflet for APO-go PEN at:

https://aguettant.ca/fileadmin/aguettant_canada/APO_GO_PEN_10MG_INJ_3ML_BRI_GB_PIL_9243356_2205.pdf on the aguettant.ca website or upon request at injectables@aguettant.ca.

The UK package leaflet for APO-go PEN is also included in the UK box of 5 pens.

A comparison of the outer and inner labels of the UK-labelled product and Movapo can be found in Table 2 of the Appendix below.

Healthcare professionals are advised that aspects of the outer and inner labels of the UK-labelled product may differ from the Movapo product that was previously marketed in Canada.

The UK-labelled product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

Reporting adverse drug reactions

Adverse drug reactions associated with the use of APO-go PEN should be reported to Aguetant Canada Inc. by e-mail at safety@aguettant.ca or by phone toll-free at 1-833-772-6294 or to

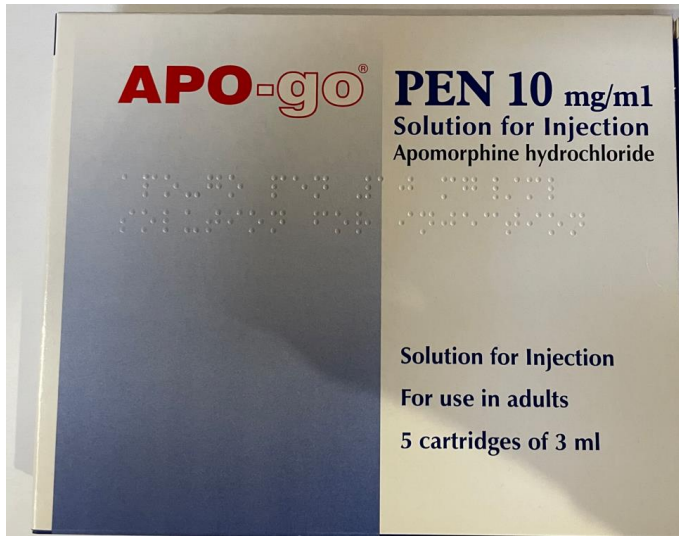
Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/drug.htm> | or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about UK-labelled APO-go PEN, please contact Aguettant Canada Inc. by phone at 514-772-6294 or toll-free at 1-833-772-6294.

Appendix

UK-labelled APO-go PEN - Product Box (box of 5 pens)



UK-labelled APO-go PEN



Table 2: Comparison of outer and inner labels of UK-labelled APO-go PEN and Movapo (previously marketed in Canada)

	UK-labelled APO-go PEN	Movapo (previously marketed in Canada)	
Outer label			DIN 02459132

APO-go[®] **PEN 10 mg/ml**
Solution for Injection
Apomorphine hydrochloride

5 cartridges of 3 ml
Each ml contains 10 mg apomorphine hydrochloride.
Each 3 ml cartridge contains 30 mg apomorphine hydrochloride.
For subcutaneous injection.

Do not store above 25°C. Keep the container in the outer carton to protect from light. Store at the same conditions after opening and between withdrawals. Do not use if the solution has turned green. Do not use if the solution is cloudy or you can see particles in it. Discard after 48 hours of first injection.

To be used as directed by the physician.
Read the package leaflet before use.

Please note: This pack does NOT contain needles. This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information. Keep this medicine out of the sight and reach of children.

Also contains:
sodium bisulphite E222, hydrochloric acid, water for injections.
Marketing Authorisation Numbers:
PL 04483/0073 (UK), PA 0593/043/001 (IE), MA 830/00302 (MT)
Marketing Authorization Holder for UK:
Britannia Pharmaceuticals Ltd., 200 Longwater Avenue,
Green Park, Reading, Berkshire RG2 6GP, UK.
Marketing Authorisation Holder for Ireland and Malta:
STADA Arzneimittel AG, Stadistraße 2-18,
61118 Bad Vilbel, Germany.

POM
Distributed by:
Britannia Pharmaceuticals Ltd., Reading, Berkshire, UK.
Clonmel Healthcare Ltd., Clonmel, Ireland.

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Pr MOVAPO^{TM/MC} **30 mg / 3 mL Injection**
(10 mg / mL)
Apomorphine Hydrochloride Injection

Pr MOVAPO^{TM/MC} **30 mg / 3 mL Injection**
(10 mg / mL)
Apomorphine Hydrochloride Injection /
Chlorhydrate d'apomorphine Injection

Do not use if the solution is cloudy, green or contains particles.
Dose: Use as your doctor has told you to. See enclosed Patient Medication Information leaflet before use.
Storage: Unopened pen: store at 25 °C (storage between 15 °C to 30 °C is acceptable). **Keep the pen in the original box to protect from light. Opened pen:** store at room temperature (15 °C to 30 °C). Throw away the pen 48 hours after opening. Keep out of reach and sight of children.
Product Monograph available on request.

Ne pas utiliser si la solution est floconneuse, verte ou contient des particules.
Dosage: Utilisez tel que recommandé par votre médecin. Voir le dépliant de renseignements pour le patient avant utilisation.
Entreposage: Stylo non utilisé: Conserver à 25 °C (entreposage entre 15 °C à 30 °C est acceptable). **Garder le stylo dans sa boîte pour le protéger de la lumière. Stylo entamé:** Conserver à température ambiante (15 °C à 30 °C). Jeter le stylo 48 heures après la première utilisation. Garder hors de la vue et de la portée des enfants.
Monographie de produit fournie sur demande.

Paladin Labs Inc. / Laboratoires Paladin inc.
St-Laurent, QC
HAM 2P2

Questions or concerns / Des questions ou des problèmes: 1-888-867-7426

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CA 001 / 9074804 1703 / 101896

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Inner
label

104881 / UK-PUL-NT 0077 00030300 1812

APO-go[®] PEN 10 mg/ml
Solution for Injection
Apomorphine hydrochloride POM
3 ml

For subcutaneous injection
Read the package leaflet before use
Britannia Pharmaceuticals Ltd. & STADA Arzneimittel AG
Batch Number:
Expiry Date:

5 10 15 20 25 30

1064200CA 00030274686 2012

Pr **MOVAPO[®]**
30 mg / 3 mL (10 mg / mL)
For SC use only /
Pour usage SC seulement
Sterile / Stérile

Paladin Labs Inc.

Lot:
EXP:

5 10 15 20 25 30 mg