



**Importation of UK-labelled Aminophylline Hydrate 25 mg / mL Solution for Injection due to the Current shortage of Canadian- authorized Aminophylline Injection**

Septa Pharmaceuticals Inc.  
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Dear: Group purchasing organizations, wholesalers, healthcare professional associations, and hospital pharmacists or pharmacies

There is a current critical shortage of Aminophylline Injection, 25 mg/mL Solution for injection in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of UK - labelled Aminophylline Hydrate 25 mg/mL Solution for Injection, with English only labels, by Septa Pharmaceuticals Inc. and has added this 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, Aminophylline Injection, 25 mg/mL Solution for injection is indicated for the symptomatic treatment of reversible bronchoconstriction associated with chronic obstructive pulmonary disease, bronchial asthma, chronic bronchitis and related bronchospastic disorders.

The UK-labelled product has the **same active ingredient (aminophylline), strength (25 mg/mL), dosage form (solution), route of administration (intravenous), product formulation, and volume** as the Canadian-authorized product.

The UK-labelled product, however, differs from the Canadian-authorized product in terms of the packaging format. The **UK-labelled product is available in 10 mL clear, one-point cut glass ampoules (single-use) with markings (from top to bottom: one white band, one green band, one yellow band and one blue dot)** while the Canadian-authorized product is available in 10 mL single-use glass vials. Caution should be used in breaking the glass ampoule and in aspirating the solution as per established institutional standard of care.

The UK-labelled product can be used in the same manner as the Canadian-authorized product. Healthcare professionals should refer to the package insert for Canadian-authorized Aminophylline Injection, 25 mg/mL Solution for injection from Omega Laboratories Limited available in English and French at <https://www.omegapharma.ca/product-detail/26> for information on the appropriate use of the product, including the:

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

#### Information on the imported product

Brand name	Dosage form and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/Importer in Canada
Aminophylline Hydrate 25 mg/mL Solution for injection	Solution for injection, Intravenous	Each 10 mL sterile solution for injection contains 250 mg aminophylline hydrate equivalent to 239.73 mg of aminophylline (25 mg in 1 mL). Also contains ethylenediamine in water for injection.  Available in cartons containing 10 x 10 mL clear, one-point cut glass ampoules (single-use).	UK  PL- 12762/0559	Mercury Pharmaceuticals Limited, UK	Septa Pharmaceuticals Inc.

Information about UK-labelled Aminophylline Hydrate 25 mg/mL Solution for Injection for reference by healthcare professionals is available in English only in the UK Summary of Product Characteristics at <https://www.medicines.org.uk/emc/product/6560/smpc/print> , in the UK package leaflet at <https://www.medicines.org.uk/emc/files/pil.6560.pdf> and in Appendix 2.

Images of the UK-labelled product can be found in Appendix 1.

Healthcare professionals are advised that aspects of the inner and outer labels of the UK-labelled product may differ from the marketed Aminophylline Injection, 25 mg/mL Solution for injection product in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

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.

### Reporting adverse drug reactions

Adverse drug reactions associated with the use of UK-labelled Aminophylline Hydrate 25 mg/mL Solution for injection should be reported to Septa Pharmaceuticals Inc. by calling +1 905-564-5665, or to [Health Canada](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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 UK-labelled Aminophylline Hydrate 25 mg/mL Solution for injection, please contact Septa Pharmaceuticals Inc. at +1 905-564-5665.

### Appendix 1

#### UK Carton:



UK Ampoule:

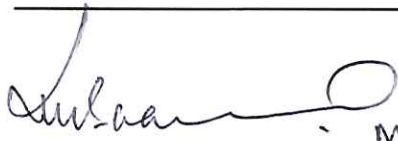


UK carton label



UK ampoule label



  
May 09 2024

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President & CEO  
Septa Pharmaceuticals Inc.