

# STERIMAX

2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

Tel.: 905-890-0636 / 800-881-3550 • Fax: 905-890-0508 / 877-546-7667 • Web: [www.sterimaxinc.com](http://www.sterimaxinc.com)

## Importation of UK-labelled Magnesium Sulfate 50% w/v Solution for Injection due to Current Shortage of Canadian-authorized Magnesium Sulfate Injection (500mg/mL, 10mL format)

Date: Thursday, October 27, 2022

Dear Healthcare professionals (physicians, surgeons, critical care and emergency room physicians, obstetricians, anesthesiologists, nurses, and pharmacists), group purchasing organizations, and sterile compounding pharmacies.

### Key messages:

- There is a critical shortage of Magnesium Sulfate Injection (500 mg/mL, 10 mL format) in Canada. To help mitigate the current shortage, Health Canada has permitted the exceptional, temporary importation and sale of equipotent Martindale Pharma's UK-labelled Magnesium Sulfate 50% w/v Solution for Injection, with English only labels, by SteriMax 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>).
- Magnesium Sulfate Injection 500 mg/mL is the same concentration as 50% w/v (or 5 g in 10 mL).
- In Canada, Magnesium Sulfate Injection (500 mg/mL) is indicated as an anticonvulsant, primarily in preeclampsia and eclampsia of pregnancy and as an electrolyte replenisher for hypomagnesemia and magnesium deficiency to maintain normal neuromuscular irritability.
- The UK-labelled product has the **same active ingredient, concentration (50% w/v solution), dosage form, volume (10 mL), and route of administration** as Canadian marketed Magnesium Sulfate Injection, but **differs with respect to the packaging format**.
- The UK-labelled product is available in ampoules while Canadian marketed Magnesium Sulfate Injection is available in vials.
- **The UK-labelled product should be used in the same manner as Canadian marketed Magnesium Sulfate Injection. Healthcare professionals should refer to the Canadian Product Monograph for marketed Magnesium Sulfate Injection (500 mg/mL) available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=19701>) for information on appropriate use including indications, contraindications, dosage and administration, diluents (sterile, preservative-free), warnings and precautions, adverse reactions, drug interactions, and storage conditions.**

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**Information on the imported product:**

Brand Name	Product Description	Packaging	Country of Authorization and Identifying Code	Authorization Holder	DEL Holder / Importer in Canada
Magnesium Sulfate <b>50% w/v</b> Solution for Injection	<b>500 mg/mL</b> of Magnesium Sulfate.  Clear, Sterile Solution (Preservative-free).  For Intravenous Infusion or Intramuscular Use Only.  Lot Number: 0135580, 0135581, 0135582  Expiry Date: 04 - 2024	Each 10 mL single-use, clear glass ampoule contains 10 mL of solution.  Available in cartons of 10 ampoules with a package insert enclosed.	United Kingdom  MIA 1883	Macarthy's Laboratories Limited T/A Martindale Pharma  Bampton Road Harold Hill Romford RM3 8UG United Kingdom	SteriMax Inc.  2770 Portland Drive, Oakville, ON, L6H 6R4 Canada

**Information for healthcare professionals**

The UK-labelled product should only be used by adequately trained professionals in a healthcare facility adequately equipped with monitoring and treatment devices for respiratory and cardiovascular support and resuscitation.

**The UK-labelled product should be used in the same manner as Canadian marketed Magnesium Sulfate Injection. Healthcare professionals should refer to the Canadian Product Monograph for marketed Magnesium Sulfate Injection (500 mg/mL) available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=19701>) for information on appropriate use including indications, contraindications, dosage and administration, diluents (sterile, preservative-free), warnings and precautions, adverse reactions, drug interactions, and storage conditions.**

Information about the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection for healthcare professionals is available for reference in English only at <https://www.medicines.org.uk/emc/product/3539/smpe>.

The UK package insert enclosed in the product carton is available for reference in English, French, and Spanish.

Images of the UK-labelled product can be found in the Appendix below. Healthcare professionals are advised that aspects of the inner and outer labels of the UK-labelled product may differ from Canadian

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marketed Magnesium Sulfate Injection. **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.

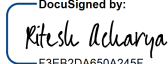
## Reporting adverse drug reactions

Adverse drug reactions associated with the use of the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection should be reported to SteriMax Inc. by calling 1-800-881-3550 or via email to [pv@sterimaxinc.com](mailto:pv@sterimaxinc.com), 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 the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection, please contact SteriMax Inc. by calling 1-800-881-3550 or via email to [medinfo@sterimaxinc.com](mailto:medinfo@sterimaxinc.com).

Original signed by:

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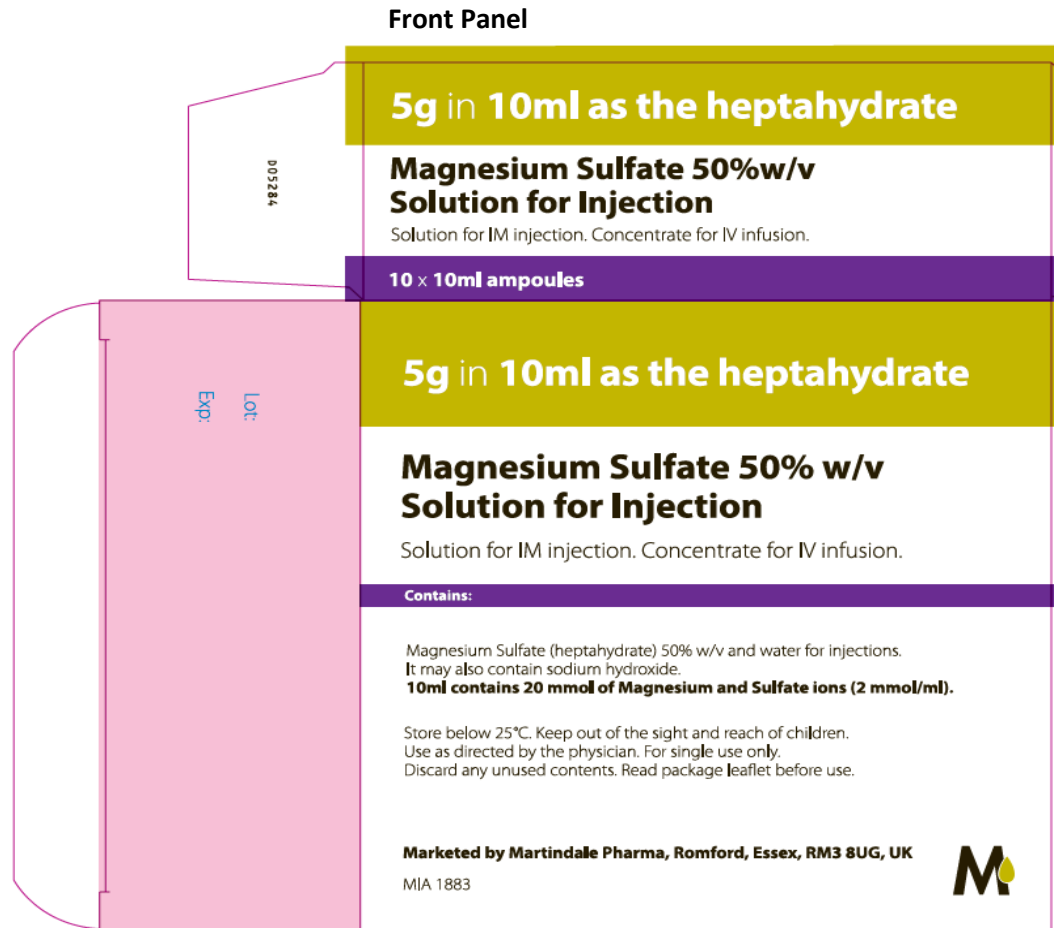
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## Appendix: Images of Martindale Pharma's UK-labelled Magnesium Sulfate 50% w/v Solution for Injection (5 g in 10 mL or 500 mg/mL)

### Ampoule Label:



### Carton Label:



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## Back Panel

10 x 10ml ampoules

Solution for IM injection. Concentrate for IV infusion.

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5g in 10ml as the heptahydrate

**5g in 10ml as the heptahydrate** M

**Magnesium Sulfate 50%w/v Solution for Injection**

Solution for IM injection  
Concentrate for IV infusion  
10ml contains 20 mmol of Magnesium and Sulfate ions (2 mmol/ml)

**MUST BE DILUTED PRIOR TO IV INFUSION**

10 x 10ml ampoules

5g in 10ml as the heptahydrate

**Magnesium Sulfate 50%w/v Solution for Injection**

10 x 10ml ampoules

## Product Images:



5g in 10ml as the heptahydrate

**Magnesium Sulfate 50% w/v Solution for Injection**

Solution for IM injection. Concentrate for IV infusion.

**Contains:**

Magnesium Sulfate (heptahydrate) 50% w/v and water for injections. It may also contain sodium hydroxide.  
**10ml contains 20 mmol of Magnesium and Sulfate ions (2 mmol/ml).**

Store below 25°C. Keep out of the sight and reach of children.  
Use as directed by the physician. For single use only.  
Discard any unused contents. Read package leaflet before use.

Marketed by Martindale Pharma, Romford, Essex, RM3 8UG, UK

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