

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

Importation of Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion by SteriMax Inc.

Date: Thursday, May 27, 2021

Audience:

Healthcare professionals (physicians, surgeons, critical care and emergency room physicians, nurses and pharmacists), and sterile compounding pharmacies.

Key Messages

- There is a shortage of Magnesium Sulfate Injection in Canada. Given the medical necessity of this product and to help mitigate the current shortage, Health Canada has not objected to the temporary importation and distribution of limited quantities of Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion by SteriMax Inc.
- In Canada, Magnesium Sulfate Injection (50% w/v or 500 mg/mL) is indicated as a Central Nervous System (CNS) depressant, primarily in preeclampsia and eclampsia of pregnancy and as an electrolyte replenisher for hypomagnesemia and magnesium deficiency to maintain normal neuromuscular irritability.
- Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion is available as a sterile solution of 50% w/v Magnesium Sulfate (as Heptahydrate) with **5 g in 10 mL** and **25 g in 50 mL** magnesium sulfate in water for injection.
- The UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion has the **same concentration (i.e., 50% w/v or 500 mg/mL solution)** and **can be used in the same manner** as the Magnesium Sulfate Injection 50% product approved and marketed in Canada.
- The UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion does not list the mg per mL strength (i.e., 500 mg/mL) on the label.
- A comparison between the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion and the Canadian-approved Magnesium Sulfate Injection 50% product can be referred to in Table 1 below.
- **For information on indications, contraindications, warnings and precautions, and dosage and administration, healthcare professionals should refer to the Canadian prescribing information for the marketed Magnesium Sulfate Injection 50% product**

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available on the Health Canada Drug Product Database: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>.

- **Multiple foreign-labelled magnesium sulfate injection products may be imported into Canada simultaneously. These products may differ, both from one another and from Canadian-approved magnesium sulfate injection products, in their routes of administration, strength and formats. At the point of use, healthcare professionals should verify each product label to confirm appropriate product selection.**
- The UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion is labelled in English only.

What is the issue?

To address a drug shortage of Magnesium Sulfate Injection in Canada, Health Canada has not objected to the temporary importation and distribution of Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion by SteriMax Inc.

Imported product

Magnesium Sulfate 50% w/v Solution for Injection or Infusion (UK-labelled product)

Manufacturer: Torbay Pharmaceuticals, Wilkins Drive, Paignton, Devon TQ4 7FG, UK

Distributor in Canada: SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information for healthcare professionals

The UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion is available as a sterile solution of 50% w/v Magnesium Sulfate (as Heptahydrate) with **5 g in 10 mL** and **25 g in 50 mL** magnesium sulfate in water for injection.

The UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion has the **same concentration (i.e. 50% w/v or 500 mg/mL solution)** and **can be used in the same manner** as the Magnesium Sulfate Injection 50% product approved and marketed in Canada.

Consistent with the Canadian-approved Magnesium Sulfate Injection 50% formulation, the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion is free of preservatives.

The following comparison between the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion and the Canadian-approved Magnesium Sulfate Injection 50% product should be noted.

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Table 1: Comparison between the UK-labelled and Canadian-approved Magnesium Sulfate Injection (50% w/v or 500 mg/mL)		
Information	Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion	Canadian-approved Magnesium Sulfate Injection 50%
Active Pharmaceutical Ingredient	Magnesium Sulfate Heptahydrate	Magnesium Sulfate Heptahydrate
Label Claim	Magnesium Sulfate Heptahydrate 50% w/v (500 mg/mL) Sulfuric Acid (pH adjuster) Water for Injection	Magnesium Sulfate Heptahydrate 50% w/v (500 mg/mL) Sulfuric Acid or Sodium Hydroxide (pH adjuster) Water for Injection
Preservative	No preservative	No preservative
Storage Conditions	Protect from light. Store between 2-25°C.	Store vials between 15 and 30°C.
Pharmaceutical Form	Sterile solution	Sterile solution
Packaging Format	10 mL glass ampoules (single-use) 50 mL glass vials (single-use)	10 mL plastic vials (single-use) 50 mL glass vials (single-use)

For information on indications, contraindications, warnings and precautions, and dosage and administration, healthcare professionals should refer to the Canadian prescribing information for the marketed Magnesium Sulfate Injection 50% product available on the Health Canada Drug Product Database: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

Information about the UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion for healthcare professionals is available at: <https://www.medicines.org.uk/emc/product/1990/smpc#gref>.

There is no DIN on the label and the lack of a bar code will prevent scanning in Canadian medication use software. 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 and prevent medication errors.

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Report health or safety concerns

Adverse drug reactions associated with the use of UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion should be reported to SteriMax Inc. by calling 1-800-881-3550 or via email to 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.

Original signed by:

DocuSigned by:

 27, 2021

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Ritesh Acharya, M. Pharm.

Executive Vice President, Scientific Affairs,
SteriMax Inc., Oakville, ON.

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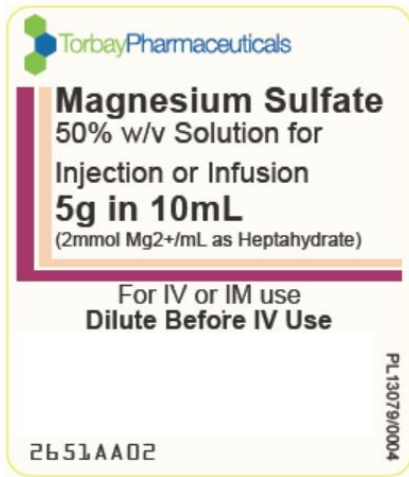
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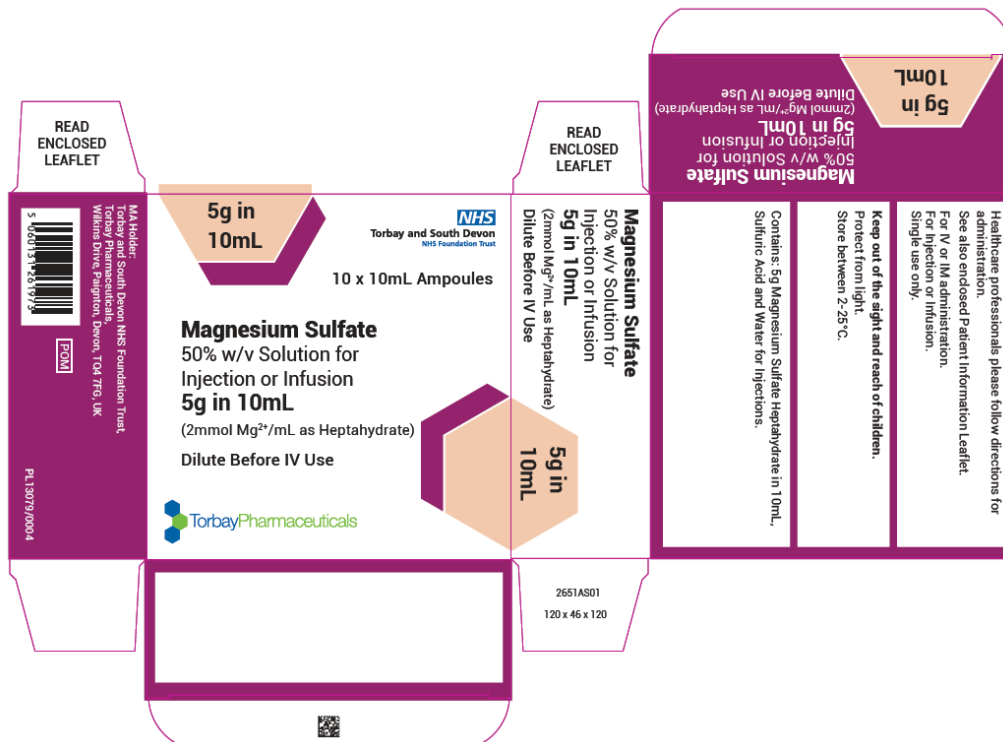
Annex – 1: Images of Torbay Pharmaceuticals' UK-labelled Magnesium Sulfate 50% w/v Solution for Injection or Infusion:

5 g in 10 mL

Ampoule Label



Carton Label



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25 g in 50 mL

Vial Label

Torbay Pharmaceuticals

Magnesium Sulfate
50% w/v Solution for Injection or Infusion
25g in 50mL
(2mmol Mg²⁺/mL as Heptahydrate)
Dilute Before IV Use

Keep out of the sight and reach of children.
For IV or IM administration.
For Injection or Infusion.
Protect from light.
Store between 2-25°C.
Single use only.
Contains 25g Magnesium Sulfate Heptahydrate in 50mL, Sulfuric Acid and Water for Injections.

Torbay Pharmaceuticals, Paignton, TQ4 7FG, UK

PL 13079/0004
POM

5 060131 261546

8296AD02

Carton Labels

25g in 50mL

Torbay Pharmaceuticals

NHS
Torbay and South Devon
NHS Foundation Trust

Magnesium Sulfate
50% w/v Solution for Injection or Infusion
25g in 50mL
(2mmol Mg²⁺/mL as Heptahydrate)
Dilute Before IV Use

BN
EXP /

10 x 50mL Vials

8296AD02

5 060131 261553

POM
PL13079/0004
MA Holder:
Torbay and South Devon
NHS Foundation Trust,
Torbay Pharmaceuticals,
Wilkins Drive, Paignton, Devon, TQ4 7FG, UK

Magnesium Sulfate
50% w/v Solution for Injection or Infusion
25g in 50mL
(2mmol Mg²⁺/mL as Heptahydrate)
Dilute Before IV Use

NHS
Torbay and South Devon
NHS Foundation Trust

Healthcare professionals please follow directions for administration.
See also enclosed Patient Information Leaflet.
For IV or IM administration.
For Injection or Infusion. Single use only.
Keep out of the sight and reach of children.
Protect from light. Store between 2-25°C.
Contains: 25g Magnesium Sulfate Heptahydrate in 50mL, Sulfuric Acid and Water for Injections.