Importation of Fresenius Kabi's US-labelled Magnesium Sulfate (1% or 10 mg/mL) in 5% Dextrose Injection, USP

2021/06/11

Audience
Healthcare professionals including Hospital Pharmacists (Hospital Pharmacists: please distribute to all Healthcare Practitioners who administer Magnesium Sulfate Injection within the hospital).

Key messages

- There is a shortage of Magnesium Sulfate Injection in Canada. Given the medical necessity of Magnesium Sulfate Injection and to help mitigate the current shortage, Health Canada has not objected to the temporary importation and distribution of Fresenius Kabi's US-labelled Magnesium Sulfate (1% or 10 mg/mL) in 5% Dextrose Injection, USP.
- The Fresenius Kabi US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP **differs** from the Fresenius Kabi Canadian-approved Magnesium Sulfate Injection, USP 50% with respect to the **indication, concentration, route of administration, and packaging**.
- As per the US Prescribing Information, the US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP is indicated for the prevention and control of seizures in pre-eclampsia and eclampsia, respectively.
- The US-labelled Magnesium Sulfate (1% or 10 mg/mL) in 5% Dextrose Injection, USP is available as a **sterile, ready-to-use solution (without any need for further dilution)**.
- The US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP is **intended for intravenous injection only**, and should **not** be used for intramuscular administration.
- The Canadian-approved Magnesium Sulfate Injection, USP 50% is available as a plastic vial, whereas the US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP is **packaged in flexible containers (freeflex® bag)**.
- **For information on appropriate use, including the indications, contraindications, warnings and precautions, and dosage and administration, healthcare professionals should refer to the US Prescribing Information for Fresenius Kabi's US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP available on the Fresenius Kabi Canada Ltd. website in English and in French:**

English version: www.fresenius-kabi.com/en-ca/magnesium-sulfate-freeflex
French-translated version: www.fresenius-kabi.com/fr-ca/magnesium-sulfate-freeflex

Healthcare professionals are advised that multiple foreign-labelled magnesium sulfate injection products may be imported and are likely to be present on the Canadian market simultaneously, contributing to the likelihood of mistake or error. 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 and use.

Imported product
Magnesium Sulfate in 5% Dextrose Injection, USP by Fresenius Kabi USA, LLC, United States.

Additional information for healthcare professionals

- The key formulation and labelling characteristics of Fresenius Kabi's US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP are indicated in the table below:

Product Name	Magnesium Sulfate in 5% Dextrose Injection, USP
Active Substance	Magnesium Sulfate
Concentration	1% (10 mg/mL)
Packaging Format	Single-dose freeflex® bag
Bag Volume	100 mL
Other Characteristics	The container (freeflex® bag) closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile
Storage	Store at 20° to 25°C (68° to 77°F). Protect from freezing.
Market Authorization Holder	Fresenius Kabi USA, LLC, United States

- Use immediately once removed from overwrap.
- For single use only – discard unused portion.
- For use only if solution is clear and container is undamaged.
- Do not add supplementary medication. Whenever possible use central route.
- After removing the overwrap, check for leaks by squeezing container. If leaks are found, discard, as sterility may be impaired.
- Overwrap is a moisture barrier and is heat-sterilized.

- For reference, the Canadian Prescribing Information for Fresenius Kabi's Canadian-approved Magnesium Sulfate Injection, USP 50% is available on the Health Canada Drug

Product Database: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html

- The US-labelled Magnesium Sulfate in 5% Dextrose Injection, USP is labelled in English only. The French-translated text of the inner and outer labels can be found in the appendices below.

- Healthcare professionals should be aware that the US-labelled product 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 and prevent medication errors.

Report health or safety concerns

Adverse drug reactions associated with the use of Fresenius Kabi's US-labelled Magnesium Sulfate (1% or 10 mg/mL) in 5% Dextrose Injection, USP in patients should be reported to Fresenius Kabi Canada Ltd.
E-mail: Canada_Vigilance@fresenius-kabi.com
Telephone: 1-877-779-7760
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

Don Truong

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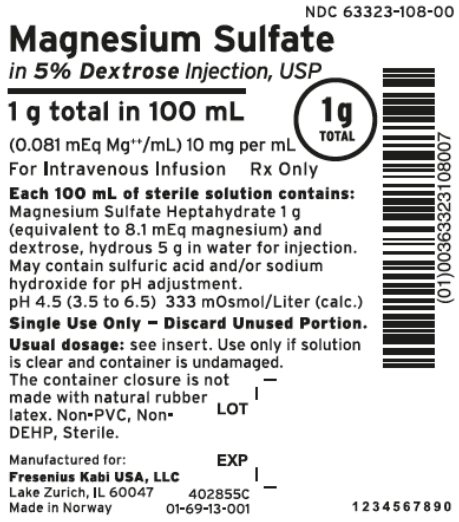
Appendices

Images of Fresenius Kabi's US-labelled Magnesium Sulfate (1% or 10 mg/mL) in 5% Dextrose Injection, USP

100 mL freeflex® bag

Inner Label



French Translation of Inner Label Text

NDC 63323-108-00

Sulfate de magnésium *dans du* ***dextrose*** *injectable à* ***5 %***

1 g au total dans 100 mL
(0,081 mEq de Mg^{++}/mL) 10 mg par mL
1 g au TOTAL
Pour perfusion intraveineuse Rx seulement

Chaque 100 mL de solution stérile contient :
Sulfate de magnésium heptahydraté 1 g (équivalant à 8,1 mEq de magnésium) et dextrose hydraté 5 g dans de l'eau pour injection.
Peut contenir de l'acide sulfurique et/ou de l'hydroxyde de sodium pour l'ajustement du pH.
pH 4,5 (3,5 à 6,5) 325 mOsmol/litre (calc.)

Usage unique exclusivement – Jeter toute portion inutilisée.

Posologie habituelle : voir la notice. N'utiliser que si la solution est limpide et si le contenant n'est pas endommagé. Ce contenant n'est pas fabriqué avec du latex de caoutchouc naturel. Sans PVC, sans DEHP et stérile.

LOT
EXP

Fabriqué pour :
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
Fabriqué en Norvège Code

Outer Label

French Translation of Outer Label Text

NDC 63323-108-00

Pour ouvrir le suremballage – déchirer à l'encoche

Sulfate de magnésium *dans du* ***dextrose*** *injectable à* ***5 %***

1 g au total dans 100 mL
(0,081 mEq de Mg^{++}/mL)
(10 mg par mL)

1 g au TOTAL

Pour perfusion intraveineuse Rx seulement

UTILISER IMMÉDIATEMENT UNE FOIS RETIRÉ DU SUREMBALLAGE.

Chaque 100 mL de solution stérile contient :
Sulfate de magnésium heptahydraté 1 g (équivalant à 8,1 mEq de magnésium) et dextrose hydraté 5 g dans de l'eau pour injection.
Peut contenir de l'acide sulfurique et/ou de l'hydroxyde de sodium pour l'ajustement du pH.
pH 4,5 (3,5 à 6,5) 325 mOsmol/litre (calc.)

Usage unique exclusivement - jeter toute portion inutilisée.

Posologie habituelle : voir la notice. N'utiliser que si la solution est limpide et si le contenant n'est pas endommagé.

NE PAS AJOUTER DE MÉDICAMENT SUPPLÉMENTAIRE. SI POSSIBLE, UTILISER LA VOIE CENTRALE.

Après avoir retiré le suremballage, comprimer le contenant pour vérifier s'il y a des fuites. S'il y a des fuites, jeter le produit car sa stérilité peut être altérée.

Le suremballage constitue une barrière contre l'humidité et est stérilisé à la chaleur.

Entreposer entre 20° et 25 °C (68° et 77 °F) [voir Température ambiante contrôlée USP].
Protéger du gel.

Ce contenant n'est pas fabriqué avec du latex de caoutchouc naturel. Sans PVC, sans DEHP et stérile.

Fabriqué pour : (logos)
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
Fabriqué en Norvège CODE

Pour ouvrir le suremballage – déchirer à l'encoche

EXP: MM/AAAA
LOT 0000000