



Importation of Fresenius Kabi's US-labelled Magnesium Sulfate in Water for Injection (4% or 40 mg/mL) and (8% or 80 mg/mL)

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 in Water for Injection (4% or 40 mg/mL) and (8% or 80 mg/mL).
- The Fresenius Kabi US-labelled Magnesium Sulfate in Water for Injection **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 Water for Injection is indicated for the prevention and control of seizures in pre-eclampsia and eclampsia, respectively.
- The US-labelled Magnesium Sulfate in Water for Injection (4% or 40 mg/mL) and (8% or 80 mg/mL) are available as **sterile, ready-to-use solutions (without any need for further dilution)**.
- The US-labelled Magnesium Sulfate in Water for Injection 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 Water for Injection 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 Water for Injection 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 Water for Injection (4% or 40 mg/mL) and (8% or 80 mg/mL) 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 Water for Injection are indicated in the table below:

Product Name	Magnesium Sulfate in Water for Injection
Active Substance	Magnesium Sulfate
Concentrations	4% (40 mg/mL) 8% (80 mg/mL)
Packaging Format	Single-dose freeflex® bag
Bag Volumes	40 mg/mL: 500 mL 80 mg/mL: 50 mL
Other Characteristics	The container (freeflex® bag) is not made with natural rubber latex, PVC, or DEHP
Storage	40 mg/mL: Store at 20° to 25°C (68° to 77°F). Protect from freezing and excessive heat. 80 mg/mL: Store at 20° to 25°C (68° to 77°F). Protect from freezing.
Market Authorization Holder	Fresenius Kabi USA, LLC, United States

- For single use only – discard unused portion.
- Do not add supplementary medication. Whenever possible use central route.
- Do not remove bag from overwrap until ready for use.
- For use only if solution is clear.

- After removing the overwrap, check for minute leaks by squeezing bag firmly. If leaks are found, discard bag, as sterility may be impaired.
- The overwrap is a moisture barrier. Use bag promptly when overwrap is opened.
- 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 Water for Injection 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 in Water for Injection (4% or 40 mg/mL) and/or (8% or 80 mg/mL) 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

Don Truong, Ph.D.

Associate Director, Medical

Fresenius Kabi Canada Ltd.

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Toronto, Ontario Canada M9W 0C8

Appendices

Images of Fresenius Kabi's US-labelled Magnesium Sulfate in Water for Injection (4% or 40 mg/mL)

500 mL freeflex® bag



Inner Label

NDC 63323-106-15

Magnesium Sulfate

in Water for Injection

20 g
TOTAL

20 g total in 500 mL
(0.325 mEq Mg⁺⁺/mL)
40 mg per mL

For Intravenous Infusion Rx Only

Each 100 mL of sterile solution contains: Magnesium Sulfate Heptahydrate 4 g (equivalent to 32.5 mEq magnesium) in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment. pH 4.5 (3.5 to 6.5). 325 mOsmol/Liter (calc.) **Single Use Only – Discard Unused Portion.**

Usual Dosage: See insert. **DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE. Do not remove bag from overwrap until ready for use.** Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing bag firmly. If leaks are found, discard bag as sterility may be impaired. The overwrap is a moisture barrier. Use bag promptly when overwrap is opened. The **freeflex**[®] bag is not made with natural rubber latex, PVC, or DEHP. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat.



363323106157

Manufactured for: **FRESENIUS KABI**
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
Made in Norway

LOT: _____
EXP: _____

freeflex[®] 1234567890

mL

French Translation of Inner Label Text

NDC 63323-106-15

Sulfate de magnésium dans de l'eau pour injection

20 g au total dans 500 mL
(0,325 mEq de Mg⁺⁺/mL)
40 mg par mL

20 g au TOTAL

Pour perfusion intraveineuse

Rx seulement

Chaque 100 mL de solution stérile contient :

Sulfate de magnésium heptahydraté 4 g (équivalent à 32,5 mEq de magnésium) 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.

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

Ne pas retirer le sac du suremballage avant d'être prêt à l'utiliser. N'utiliser que si la solution est limpide. Après avoir retiré le suremballage, comprimer fermement le sac pour vérifier la présence d'infimes fuites. S'il y a des fuites, jeter le sac car la stérilité du produit peut être altérée.

Le suremballage est une barrière contre l'humidité. Utiliser le sac rapidement après l'ouverture du suremballage.

Le sac **Freeflex**^{MD} n'est pas fabriqué avec du latex de caoutchouc naturel, ni avec du PVC ou du DEHP.

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

Fabriqué pour : (logos)

Fresenius Kabi USA, LLC

Lake Zurich, IL 60047

Fabriqué en Norvège

CODE

Outer Label

Product No. 610615

Magnesium Sulfate 500 mL x 24


in Water for Injection

20 g total in 500 mL (40 mg per mL)


NDC 63323-106-15 Rx only

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from freezing.


Manufactured for:
FRESENIUS KABI
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
www.fresenius-kabi.com/us
Made in Norway



EXP: MM-DD-YYYY LOT: 0000000 QTY: 24



(17) YYMMDD (10) 0000000 (30) 24



(01) 30363323 106158 (21) 000000000000

63611
FUH 0223 01-82-13-003B

French Translation of Outer Label Text

Produit n° 610615

Sulfate de magnésium 500 mL x 24

dans de l'eau pour injection

20 g au total dans 500 mL (40 mg par mL)

NDC 63323-106-15 Rx seulement

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

Fabriqué pour :
FRESENIUS KABI
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
www.fresenius-kabi.com/us
Fabriqué en Norvège



EXP: MM-DD-YYYY LOT: 0000000 QTY: 24



(17) YYMMDD (10) 0000000 (30) 24



(01) 30363323 106158 (21) 000000000000

63611
FUH 0223 01-82-13-003B

Images of Fresenius Kabi's US-labelled Magnesium Sulfate in Water for Injection (8% or 80 mg/mL)

50 mL freeflex® bag



Inner Label

NDC 63323-107-01

Magnesium Sulfate
in Water for Injection

4 g
TOTAL

4 g total in 50 mL
(0.65 mEq Mg⁺⁺/mL)
80 mg per mL

For Intravenous Infusion Rx Only

Each 50 mL of sterile solution contains:
Magnesium Sulfate Heptahydrate 4 g
(equivalent to 32.5 mEq magnesium) in
water for injection. May contain sulfuric acid
and/or sodium hydroxide for pH adjustment.
pH 4.5 (3.5 to 6.5) 649 mOsmol/Liter (calc.)

Single Use Only – Discard Unused Portion.
Usual Dosage: See insert. The **freeflex**[®] bag
is not made with natural rubber –
latex, PVC, or DEHP.

LOT |

Manufactured for:
 **FRESENIUS
KABI** EXP |
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047 402854B —
Made in Norway 01-69-13-002 1 2 3 4 5 6 7 8 9 0



(01)00363323107017

French Translation of Inner Label Text

NDC 63323-107-01

Sulfate de magnésium dans de l'eau pour injection

4 g au total dans 50 mL
(0,65 mEq de Mg⁺⁺/mL)
80 mg par mL

4 g au TOTAL

Pour perfusion intraveineuse

Rx seulement

Chaque 50 mL de solution stérile contient :

Sulfate de magnésium heptahydraté 4 g (équivalent à 32,5 mEq de magnésium) 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. Le sac Freeflex^{MD} n'est pas fabriqué avec du latex de caoutchouc naturel, ni avec du PVC ou du DEHP.

LOT
EXP

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

CODE

Outer Label

To Open Overwrap – Tear at Notch

NDC 63323-107-01

Magnesium Sulfate

in Water for Injection

4g
TOTAL

4 g total in 50 mL
(0.65 mEq Mg⁺⁺/mL)
80 mg per mL

For Intravenous Infusion

Rx Only

Each 50 mL of sterile solution contains: Magnesium Sulfate Heptahydrate 4 g (equivalent to 32.5 mEq magnesium) in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment. pH 4.5 (3.5 to 6.5) 649 mOsmol/Liter (calc.)

Single Use Only – Discard Unused Portion. Usual Dosage: See insert.

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.

Do not remove bag from overwrap until ready for use. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing bag firmly. If leaks are found, discard bag as sterility may be impaired.

The overwrap is a moisture barrier. Use bag promptly when overwrap is opened.

The freeflex[®] bag is not made with natural rubber latex, PVC, or DEHP.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.

Manufactured for:

 **FRESENIUS
KABI**

Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
Made in Norway

 free flex[®]



French Translation of Outer Label Text

NDC 63323-107-01

Pour ouvrir le suremballage – déchirer à l’encoche

Sulfate de magnésium *dans de l’eau pour injection*

4 g au total dans 50 mL
(0,65 mEq de Mg⁺⁺/mL)
80 mg par mL

4 g au TOTAL

Pour perfusion intraveineuse

Rx seulement

Chaque 50 mL de solution stérile contient : Sulfate de magnésium heptahydraté 4 g (équivalent à 32,5 mEq de magnésium) 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) 649 mOsmol/Litre (calc.)

Usage unique exclusivement – Jeter toute portion inutilisée. Posologie habituelle : voir la notice.

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

Ne pas retirer le sac du suremballage avant d’être prêt à l’utiliser. N’utiliser que si la solution est limpide. Après avoir retiré le suremballage, comprimer fermement le sac pour vérifier la présence d’infimes fuites. S’il y a des fuites, jeter le sac car la stérilité du produit peut être altérée.

Le suremballage est une barrière contre l’humidité. Utiliser le sac rapidement après l’ouverture du suremballage.

Le sac **Freeflex**^{MD} n’est pas fabriqué avec du latex de caoutchouc naturel, ni avec du PVC ou du DEHP.

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

Protéger du gel.

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