MAGNESIUM SULFATE IN WATER- magnesium sulfate in water injection, solution Hospira, Inc.

MAGNESIUM SULFATE IN WATER FOR INJECTION

Flexible Plastic Container

For Intravenous Use Only

Rx only

DESCRIPTION

Magnesium Sulfate in Water for Injection is a sterile, nonpyrogenic solution of magnesium sulfate heptahydrate in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment. The pH is 4.5 (3.5 to 6.5). It is available in 4% and 8% concentrations. See **HOW SUPPLIED** section for the content and characteristics of available dosage forms and sizes.

Magnesium Sulfate, USP heptahydrate is chemically designated MgSO₄ • 7H₂O, colorless crystals or white powder freely soluble in water.

Water for Injection, USP is chemically designated H_2O .

Water can permeate from inside the flexible plastic container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

Magnesium (Mg⁺⁺) is an important cofactor for enzymatic reactions and plays an important role in neurochemical transmission and muscular excitability.

Magnesium prevents or controls convulsions by blocking neuromuscular transmission and decreasing the amount of acetylcholine liberated at the end plate by the motor nerve impulse. Magnesium is said to have a depressant effect on the central nervous system, but it does not adversely affect the mother, fetus or neonate when used as directed in eclampsia or pre-eclampsia. Normal serum magnesium levels range from 1.3 to 2.1 mEq/liter.

As serum magnesium rises above 4 mEq/liter, the deep tendon reflexes are first decreased and then disappear as the serum level approaches 10 mEq/liter. At this level respiratory paralysis may occur. Heart block also may occur at this or lower serum levels of magnesium.

Magnesium acts peripherally to produce vasodilation. With low doses only flushing and sweating occur, but larger doses cause lowering of blood pressure. The central and peripheral effects of magnesium poisoning are antagonized to some extent by intravenous administration of calcium.

With intravenous administration the onset of anticonvulsant action is immediate and lasts about 30 minutes. Following intramuscular administration the onset of action occurs in about one hour and persists for three to four hours. Effective anticonvulsant serum levels range from 2.5 to 7.5 mEq/liter.

Pharmacokinetics:

Absorption: Intravenously administered magnesium is immediately absorbed.

Distribution: Approximately 1-2% of total body magnesium is located in the extracellular fluid space. Magnesium is 30% bound to albumin.

Metabolism: Magnesium is not metabolized.

Excretion: Magnesium is excreted solely by the kidney at a rate proportional to the serum concentration and glomerular filtration.

Special Populations:

Renal Insufficiency: Magnesium is excreted solely by the kidney. In patients with severe renal insufficiency, the dose should be lower and frequent serum magnesium levels must be obtained (see **DOSAGE AND ADMINISTRATION**).

Hepatic Insufficiency: Magnesium is excreted solely by the kidney. No dosing adjustments are necessary in hepatic insufficiency.

Drug-Drug Interactions: Drug induced renal losses of magnesium occur with the following drugs or drug classes:

Aminoglycosides	Amphotericin B
Cyclosporine	Diuretics
Digitalis	Cisplatin
Alcohol	

INDICATIONS AND USAGE

Magnesium Sulfate in Water for Injection is indicated for the prevention and control of seizures in preeclampsia and eclampsia, respectively. When used judiciously it effectively prevents and controls the convulsions of eclampsia without producing deleterious depression of the central nervous system of the mother or infant. However, other effective drugs are available for this purpose.

CONTRAINDICATIONS

Intravenous magnesium should not be given to mothers with toxemia of pregnancy during the two hours preceding delivery.

WARNINGS

FETAL HARM: Continuous administration of magnesium sulfate beyond 5-7 days to pregnant women can lead to hypocalcemia and bone abnormalities in the developing fetus. These bone abnormalities include skeletal demineralization and osteopenia. In addition, cases of neonatal fracture have been reported. The shortest duration of treatment that can lead to fetal harm is not known. Magnesium sulfate should be used during pregnancy only if clearly needed. If magnesium sulfate is given for treatment of preterm labor, the woman should be informed that the efficacy and safety of such use have not been established and that use of magnesium sulfate beyond 5-7 days may cause fetal abnormalities.

Parenteral use in the presence of renal insufficiency may lead to magnesium intoxication.

PRECAUTIONS

Because magnesium is removed from the body solely by the kidneys, the drug should

be used with caution in patients with renal impairment. Urine output should be maintained at a level of 100 mL every four hours. Monitoring serum magnesium levels and the patient's clinical status is essential to avoid the consequences of overdosage in toxemia. Clinical indications of a safe dosage regimen include the presence of the patellar reflex (knee jerk) and absence of respiratory depression (approximately 16 breaths or more/minute). Serum magnesium levels usually sufficient to control convulsions range from 3 to 6 mg/100 mL (2.5 to 5 mEq/liter). The strength of the deep tendon reflexes begins to diminish when serum magnesium levels exceed 4 mEq/liter. Reflexes may be absent at 10 mEq magnesium/liter, where respiratory paralysis is a potential hazard. An injectable calcium salt should be immediately available to counteract the potential hazards of magnesium intoxication in eclampsia.

Magnesium Sulfate in Water for Injection should be administered slowly to avoid producing hypermagnesemia.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Magnesium Sulfate in Water for Injection have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy (See WARNINGS and PRECAUTIONS)

Teratogenic Effects:

Magnesium Sulfate in Water for Injection, can cause fetal abnormalities when administered beyond 5-7 days to pregnant women. There are retrospective epidemiological studies and case reports documenting fetal abnormalities such as hypocalcemia, skeletal demineralization's, osteopenia and other I skeletal abnormalities with continuous maternal administration of magnesium sulfate for more than 5-7 days.¹⁻ ¹² Magnesium Sulfate in Water for Injection should be used during pregnancy only if clearly needed. If this drug is used during pregnancy the woman should be apprised of the potential harm to the fetus.

Nonteratogenic Effects:

When administered by continuous IV infusion (especially for more than 24 hours preceding delivery) to control convulsions in a toxemic woman, the newborn may show signs of magnesium toxicity, including neuromuscular or respiratory depression. (See **OVERDOSAGE.**)

Labor and Delivery:

Continuous administration of magnesium sulfate is an unapproved treatment for preterm labor. The safety and efficacy of such use have not been established. The administration of Magnesium Sulfate in Water for Injection outside of its approved indication in pregnant women should be by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Magnesium Sulfate in Water for Injection is administered to a nursing mother.

ADVERSE REACTIONS

The adverse effects of parenterally administered magnesium usually are the result of magnesium intoxication. These include flushing, sweating, hypotension, depressed reflexes, flaccid paralysis, hypothermia, circulatory collapse, cardiac and central nervous system depression proceeding to respiratory paralysis.

Hypocalcemia with signs of tetany secondary to magnesium sulfate therapy for eclampsia has been reported.

OVERDOSAGE

Magnesium intoxication is manifested by a sharp drop in blood pressure and respiratory paralysis. Disappearance of the patellar reflex is a useful clinical sign to detect the onset of magnesium intoxication. In the event of overdosage, artificial ventilation must be provided until a calcium salt can be injected IV to antagonize the effects of magnesium.

For Treatment of Overdose

Artificial respiration is often required. Intravenous calcium, 10 to 20 mL of a 5% solution (diluted if desirable) with isotonic sodium chloride for injection) is used to counteract effects of hypermagnesemia. Subcutaneous physostigmine, 0.5 to 1 mg may be helpful.

Hypermagnesemia in the newborn may require resuscitation and assisted ventilation via endotracheal intubation or intermittent positive pressure ventilation as well as IV calcium.

DOSAGE AND ADMINISTRATION

Magnesium Sulfate in Water for Injection is intended for intravenous use only. For the management of pre-eclampsia or eclampsia, intravenous infusions of dilute solutions of magnesium (1% to 8%) are often given in combination with intramuscular injections of 50% Magnesium Sulfate Injection, USP. Therefore, in the clinical conditions cited below, both forms of therapy are noted, as appropriate.

<u>Continuous maternal administration of magnesium sulfate in pregnancy beyond 5-7</u> <u>days can cause fetal abnormalities.</u>

In Eclampsia

In severe pre-eclampsia or eclampsia, the total initial dose is 10 to 14 g of magnesium sulfate. To initiate therapy, 4 g of Magnesium Sulfate in Water for Injection may be administered intravenously. The rate of I.V. infusion should generally not exceed 150 mg/minute, or 3.75 mL of a 4% concentration (or its equivalent) per minute, except in severe eclampsia with seizures. Simultaneously, 4 to 5 g (32.5 to 40.6 mEq) of magnesium sulfate may be administered intramuscularly into each buttock using undiluted 50% Magnesium Sulfate Injection, USP. After the initial I.V. dose, some clinicians administer 1 to 2 g/hour by constant I.V. infusion.

Subsequent intramuscular doses of 4 to 5 g of magnesium sulfate may be injected into alternate buttocks every four hours, depending on the continuing presence of the patellar reflex, adequate respiratory function, and absence of signs of magnesium toxicity. Therapy should continue until paroxysms cease.

A serum magnesium level of 6 mg/100 mL is considered optimal for control of seizures. A total daily (24 hr) dose of 30 to 40 g magnesium sulfate should not be exceeded. In the presence of severe renal insufficiency, frequent serum magnesium concentrations must be obtained and the maximum dosage of magnesium sulfate is 20 g per 48 hours.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Do not administer unless solution is clear. Discard unused portion.

HOW SUPPLIED

Magnesium Sulfate in Water for Injection is supplied in single-dose flexible plastic containers as follows:

		Total	Total	Magnesium	Magnesium	
NDC Number		Magnesium	Magnesium	Sulfate*	lon	Osmolarity
(Unit of Sale)	Concentration	Sulfate*	lon	Concentration	Concentration	(calc.)

	1		1	1		1 1
NDC 0409-						
6729-23						
Case of 24 single-dose						
flexible plastic	4 g/100 mL				32.5 mEq/100	325
containers	(40 mg/mL)	4 g	32.5 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC 0409-	(101119,1112)	. 9	021011129	1/0 (10 mg,m_)		
4121-50						
Case of 50						
single-dose						
flexible plastic	4 g/100 mL				32.5 mEq/100	325
containers	(40 mg/mL)	4 g	32.5 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC 0409-						
6729-03						
Case of 24						
single-dose						225
flexible plastic containers	20 g/500 mL	20 a	162.2 mEa	10/(10 mg/ml)	32.5 mEq/100 mL	325
NDC 0409-	(40 mg/mL)	20 g	102.5 IIIEQ	4% (40 mg/mL)	111	mOsmol/Liter
2050-20						
Case of 20						
single-dose						
flexible plastic	20 g/500 mL				32.5 mEq/100	325
containers	(40 mg/mL)	20 g	162.3 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC						
0409- 6729-09						
Case of						
12 single-						
dose						
flexible						
plastic						
containers					32.5 mEq/100	325
	(40 mg/mL)	40 g	325 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC 0409-						
3164-12 Case of 12						
single-dose						
flexible plastic	40 g/1000 mL				32.5 mEq/100	325
containers	(40 mg/mL)	40 g	325 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC 0409-		3	•			
6729-24						
Case of 24						
single-dose						
flexible plastic	2 g/50 mL [†]	2	1005 5		16.25 mEq/50	325
containers	(40 mg/mL)	2 g	16.25 mEq	4% (40 mg/mL)	mL	mOsmol/Liter
NDC						
0409-						
5239-60						
Case of						
60 single-						
dose						
flexible						
plastic	2 g/50 mL [†]				16.25 mEq/50	325
containers	2 g/50 mL ⁻ (40 mg/mL)	2 g	16.25 mFg	4% (40 mg/mL)	-	mOsmol/Liter
	(TO HIG/IIIL)	2 y	10.20 IIILY	ייע (דע וווט/וווב)	111	

NDC 0409- 6730-13 Case of 24 single-dose flexible plastic containers	4 g/50 mL [†] (80 mg/mL)	4 g	32.5 mEq	8% (80 mg/mL)	32.5 mEq/50 mL	649 mOsmol/Liter
NDC 0409- 6730-60 Case of 60 single- dose flexible plastic containers	4 g/50 mL [†] (80 mg/mL)	4 g	32.5 mEq	8% (80 mg/mL)	32.5 mEq/50 mL	649 mOsmol/Liter

* As the heptahydrate.

† Partial fill container 50 mL volume in 100 mL container.

WARNING: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

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

REFERENCES

- 1. Yokoyama K, Takahashi N, Yada Y. Prolonged maternal magnesium administration and bone metabolism in neonates. *Early Human Dev.* 2010; 86(3):187-91. Epub 2010 Mar 12.
- 2. Wedig KE, Kogan J, Schorry EK et al. Skeletal demineralization and fractures caused by fetal magnesium toxicity. *J Perinatol.* 2006; 26(6):371-4.
- 3. Nassar AH, Sakhel K, Maarouf H, et al. Adverse maternal and neonatal outcome of prolonged course of magnesium sulfate tocolysis. *Acta Obstet Gynecol Scan*. 2006;85(9):1099-103.
- 4. Malaeb SN, Rassi A, Haddad MC. Bone mineralization in newborns whose mothers received magnesium sulphate for tocolysis of premature labor. *Pediatr Radiol.* 2004;34(5):384-6. Epub 2004 Feb 18.
- 5. Matsuda Y, Maeda Y, Ito M, et al. Effect of magnesium sulfate treatment on neonatal bone abnormalities. *Gynecol Obstet Invest*. 1997; 44(2):82-8.
- 6. Schanler RJ, Smith LG, Burns PA. Effects of long-term maternal intravenous magnesium sulfate therapy on neonatal calcium metabolism and bone mineral content. *Gynecol Obstet Invest.* 1997; 43(4):236-41.
- Santi MD, Henry GW, Douglas GL. Magnesium sulfate treatment of preterm labor as a cause of abnormal neonatal bone mineralization. *J Pediatr Orthop*. 1994; 14(2):249-53.
- 8. Holocomb WL, Shackelford GD, Petrie RH. Magnesium tocolysis and neonatal bone abnormalities: a controlled study. *Obstet Gynecol.* 1991; 78(4):611-4.
- 9. Cumming WA, Thomas VJ. Hypermagnesemia: a cause of abnormal metaphyses in the neonate. *Am J Roentgenol.* 1989; 152(5):1071-2.
- 10.Lamm CL, Norton KL, Murphy RJ. Congenital rickets associated with magnesium sulfate infusion for tocolysis. *J Pediatr*. 1988; 113(6):1078-82.
- 11.McGuinness GA, Weinstein MM, Cruikshank DP, et al. Effects of magnesium sulfate treatment on perinatal calcium metabolism. II. Neonatal responses. *Obstet Gynecol.* 1980;56(5):595-600.
- 12.Riaz M, Porat R, Brodsky NL, et al. The effect of maternal magnesium sulfate treatment on newborns: a prospective controlled study. *J Perinatol.* 1998; 18(6 pt

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PRINCIPAL DISPLAY PANEL - 50 mL Bag Label

50 mL NDC 0409-6730-11

MAGNESIUM SULFATE IN WATER FOR INJECTION 4 g/50 mL (80 mg/mL)

4g TOTAL

EACH 50 mL 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-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR INTRAVENOUS USE. RECOMMENDED DOSAGE: SEE PRESCRIBING INFORMATION. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

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IM-5199

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PRINCIPAL DISPLAY PANEL - 50 mL Bag Pouch Label

50 mL TO OPEN – TEAR AT NOTCH NDC 0409-6730-11

MAGNESIUM SULFATE IN WATER FOR INJECTION

4 g/50 mL (80 mg/mL)

4g TOTAL

Each 50 mL 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.

649 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP

Controlled Room Temperature.] Protect from freezing. See prescribing information. Not Made With Natural Rubber Latex.

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7 OTHER

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PRINCIPAL DISPLAY PANEL - 50 mL Bag Label - NDC 0409-6730-50

50 mL NDC 0409-6730-50 Magnesium Sulfate in Water for Injection 4 g/50 mL (80 mg/mL) 4g TOTAL

Each 50 mL 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-dose container. Discard unused portion. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections.

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Hospira

12165-02

LOT:12345678 EXP:mm-yyyy



PRINCIPAL DISPLAY PANEL - 50 mL Bag Pouch Label - NDC 0409-6730-50

50 mL NDC 0409-6730-50

Magnesium Sulfate

in Water for Injection 4 g/50 mL (80 mg/mL) 4 g TOTAL Each 50 mL 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. 649 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See prescribing information.

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13090-01

50 mL

NDC 0409-6730-50

TOTAL

Magnesium Sulfate

in Water for Injection 4 g/50 mL (80 mg/mL)

Each 50 mL 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. 649 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See prescribing information.

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PRINCIPAL DISPLAY PANEL - 50 mL Bag Overwrap Back

Magnesium Sulfate

in Water for Injection 4 g/50 mL (80 mg/mL) 4 g TOTAL



PRINCIPAL DISPLAY PANEL - 100 mL Bag Label

100 mL NDC 0409-6729-41

MAGNESIUM SULFATE IN WATER FOR INJECTION

4 g/100 mL (40 mg/mL)

4g TOTAL

EACH 100 mL 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-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR INTRAVENOUS USE. RECOMMENDED DOSAGE: SEE PRESCRIBING INFORMATION. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

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PRINCIPAL DISPLAY PANEL - 100 mL Bag Pouch Label

100 mL TO OPEN – TEAR AT NOTCH NDC 0409-6729-41

MAGNESIUM SULFATE IN WATER FOR INJECTION

4 g/100 mL (40 mg/mL)

4g TOTAL

Each 100 mL 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.

325 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP

Controlled Room Temperature.] Avoid excessive heat. Protect from freezing. See prescribing information. Not Made With Natural Rubber Latex.

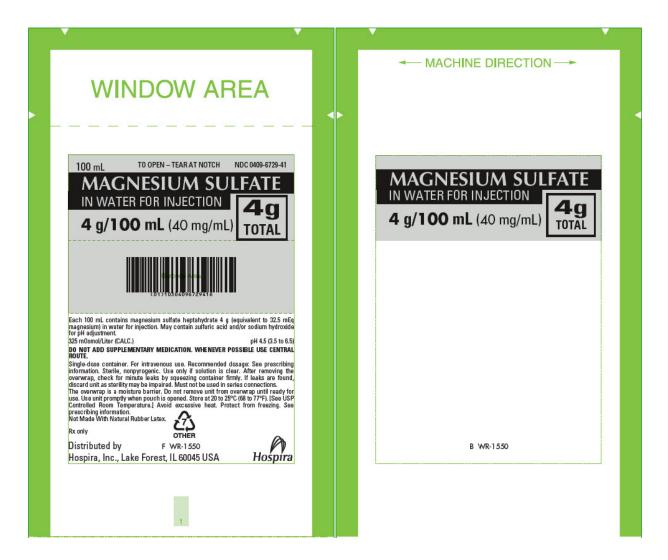
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F WR-1550

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PRINCIPAL DISPLAY PANEL - 500 mL Bag Label

500 mL NDC 0409-6729-21

20 g TOTAL

MAGNESIUM SULFATE

IN WATER FOR INJECTION 20 g/500 mL (40 mg/mL)

EACH 100 mL 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-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR INTRAVENOUS USE. RECOMMENDED DOSAGE: SEE PRESCRIBING INFORMATION. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

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PRINCIPAL DISPLAY PANEL - 40 mg/mL Bag Overwrap - 500 mL

TO OPEN TEAR AT NOTCH

2

HDPE

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING

THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT. 98-4321-R14-3/98

TO OPEN TEAR AT NOTCH



DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT. 98-4321-R14-3/98

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label

1000 mL NDC 0409-6729-31

MAGNESIUM SULFATE IN WATER FOR INJECTION

40 g TOTAL

40 g/1000 mL (40 mg/mL)

EACH 100 mL 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-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR INTRAVENOUS USE. RECOMMENDED DOSAGE: SEE PRESCRIBING INFORMATION. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

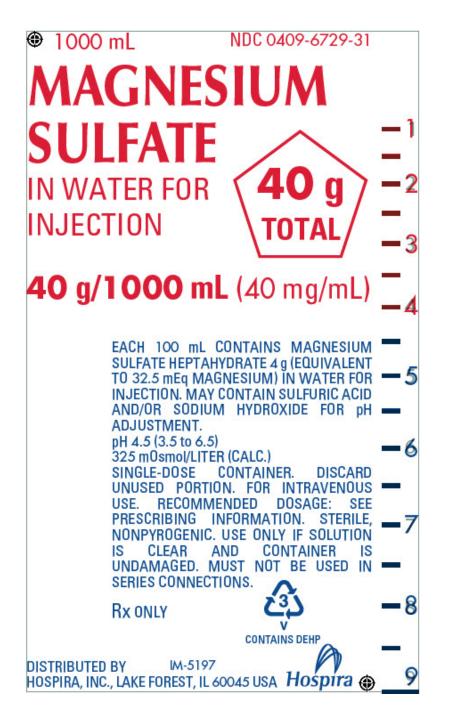
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PRINCIPAL DISPLAY PANEL - 40 mg/mL Bag Overwrap - 1000 mL

TO OPEN TEAR AT NOTCH

2

HDPE

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT. 98-4321-R14-3/98

TO OPEN TEAR AT NOTCH



DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT. 98-4321-R14-3/98

PRINCIPAL DISPLAY PANEL - 2 g/50 mL Bag Label

50 mL NDC 0409-6729-11

MAGNESIUM SULFATE IN WATER FOR INJECTION

2g TOTAL

2 g/50 mL (40 mg/mL)

EACH 50 mL CONTAINS MAGNESIUM SULFATE HEPTAHYDRATE 2 g (EQUIVALENT TO 16.25 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-DOSE CONTAINER. DISCARD UNUSED PORTION. FOR INTRAVENOUS USE. RECOMMENDED DOSAGE: SEE PRESCRIBING INFORMATION. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

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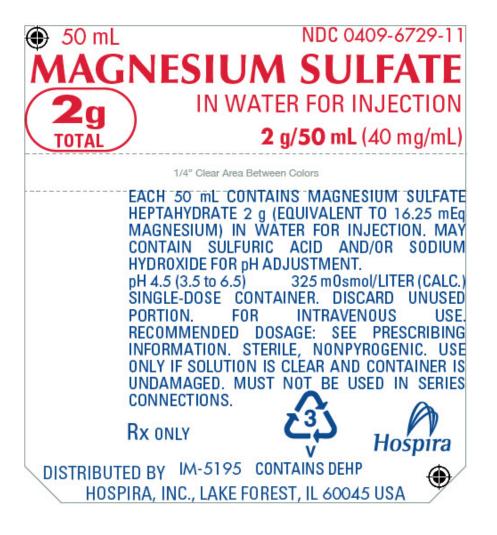
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Hospira

IM-5195

DISTRIBUTED BY HOSPIRA, INC., LAKE FOREST, IL 60045 USA



PRINCIPAL DISPLAY PANEL - 2 g/50 mL Bag Pouch Label

50 mL TO OPEN – TEAR AT NOTCH NDC 0409-6729-11

MAGNESIUM SULFATE IN WATER FOR INJECTION

2 g TOTAL

2 g/50 mL (40 mg/mL)

Each 50 mL contains magnesium sulfate heptahydrate 2 g (equivalent to 16.25 mEq magnesium) in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment.

325 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP

Controlled Room Temperature.] Protect from freezing. See prescribing information. Not Made With Natural Rubber Latex

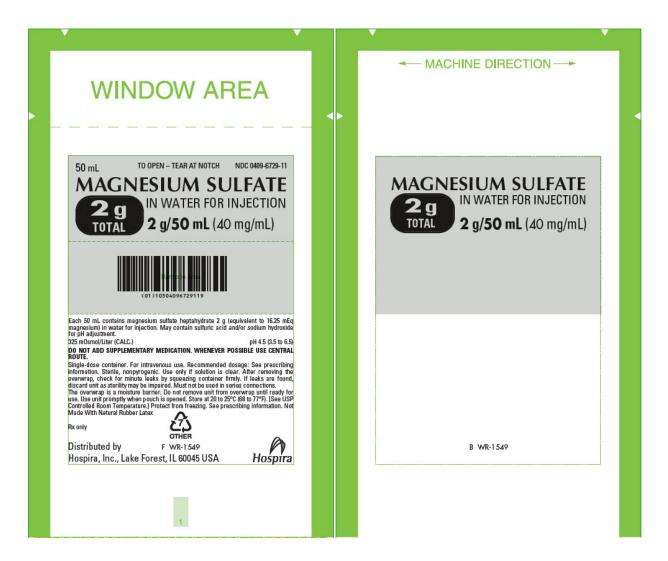
Rx only

7 OTHER

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F WR-1549

Hospira



PRINCIPAL DISPLAY PANEL - 4 g/100 mL Bag Label

100 mL NDC 0409-4121-01

Magnesium Sulfate in Water for Injection

4 g TOTAL

4 g/100 mL (40 mg/mL)

Each 100 mL 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-dose container. Discard unused portion. For intravenous use. Recommended dosage: see prescribing information. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections.

Rx ONLY

5 PP

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Lake Forest, IL 60045 USA

Hospira

12137-02

LOT:12345678 EXP:mm-yyyy



PRINCIPAL DISPLAY PANEL - 4 g/100 mL Bag Pouch Label

100 mL NDC 0409-4121-01

Magnesium Sulfate

in Water for Injection 4 g/100 mL (40 mg/mL)

4 g TOTAL

Each 100 mL 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.

325 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Avoid excessive heat. Protect from freezing. See prescribing information.

Not Made With Natural Rubber Latex

Rx ONLY

7 OTHER

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Hospira

13093-01

100 mL

NDC 0409-4121-01

4g

TOTAL

Magnesium Sulfate

in Water for Injection 4 **q/100 mL** (40 mg/mL)

Each 100 mL 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. 325 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

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

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Avoid excessive heat. Protect from freezing. See prescribing information.



PRINCIPAL DISPLAY PANEL - 100 mL Bag Overwrap Back

Magnesium Sulfate

in Water for Injection 4 g/100 mL (40 mg/mL)4 g TOTAL 13097-01



PRINCIPAL DISPLAY PANEL - 20 g/500 mL Bag Label

500 mL NDC 0409-2050-01

Magnesium Sulfate in Water for Injection

20 a TOTAL

20 g/500 mL (40 mg/mL)

Each 100 mL contains magnesium sulfate heptahydrate 4 g (equivalent to 32.5 mEg 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-dose container. Discard unused portion. For

intravenous use. Recommended dosage: see prescribing information. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections. Inspect bag by squeezing firmly. If leaks are found, discard.

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

Do not remove from overwrap until ready for use.

Rx ONLY

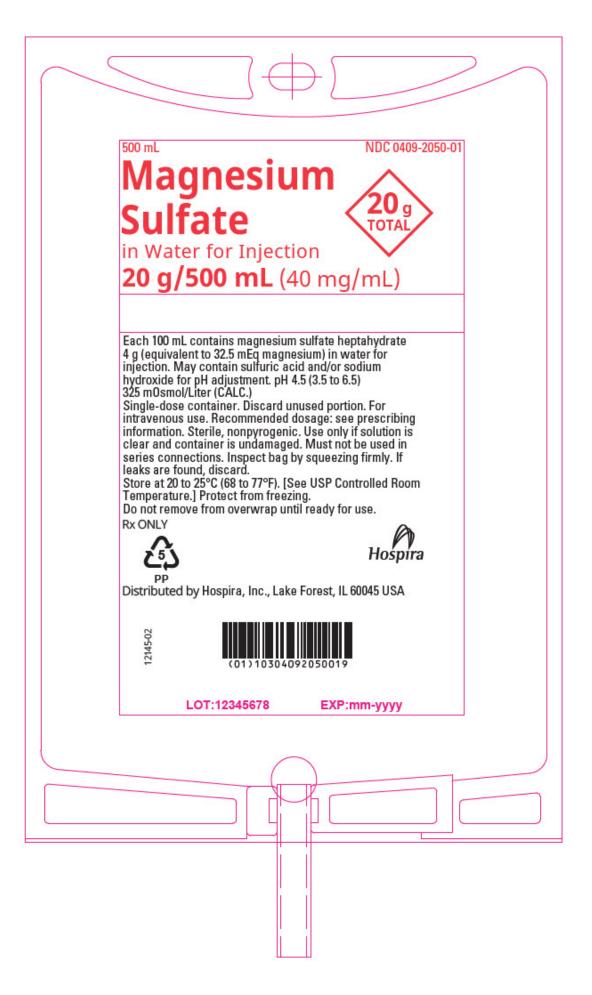
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12145-02

LOT:12345678 EXP:mm-yyyy



PRINCIPAL DISPLAY PANEL - 40 g/1000 mL Bag Label

1000 mL NDC 0409-3164-01

Magnesium Sulfate in Water for Injection

40 g TOTAL

40 g/1000 mL (40 mg/mL)

Each 100 mL 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-dose container. Discard unused portion. For intravenous use.

Recommended dosage: See prescribing information.

Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections.

Inspect bag by squeezing firmly. If leaks are found, discard.

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

Do not remove from overwrap until ready for use.

Rx ONLY

5 PP

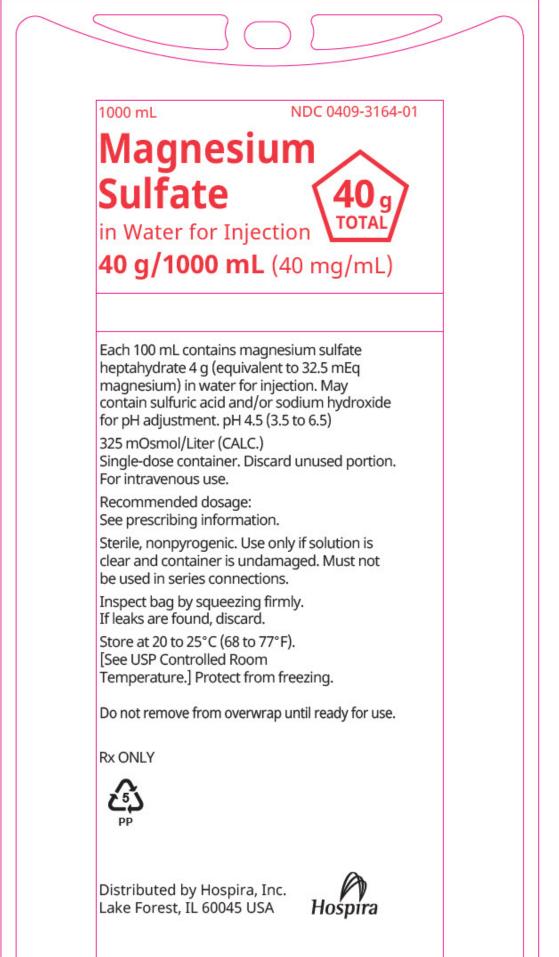
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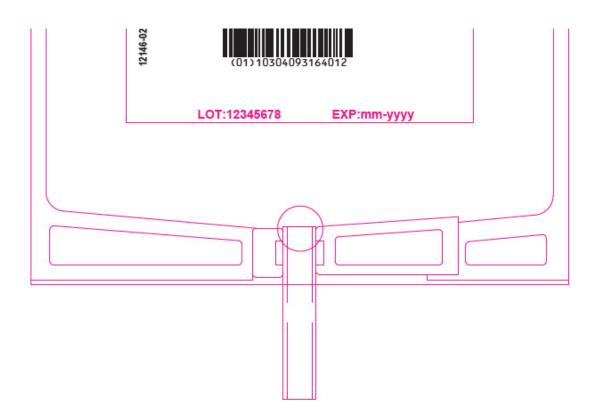
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Hospira

12146-02

LOT:12345678 EXP:mm-yyyy





PRINCIPAL DISPLAY PANEL -2 g/50 mL Bag Label - 0409-5239

50 mL NDC 0409-5239-01

Magnesium Sulfate in Water for Injection

2 g TOTAL

2 g/50 mL (40 mg/mL)

Each 50 mL contains magnesium sulfate heptahydrate 2 g (equivalent to 16.25 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-dose container. Discard unused portion. For intravenous use. Recommended dosage: see prescribing information. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections.

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Rx ONLY
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5 PP

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Hospira

12136-02

LOT:12345678 EXP:mm-yyyy

50 mL Magnesium Sulfate in Water for Injection 2 g/50 mL (40 mg/mL) NDC 0409-5239-01 2 g TOTAL
Each 50 mL contains magnesium sulfate heptahydrate 2 g (equivalent to 16.25 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-dose container. Discard unused portion. For intravenous use, Recommended dosage: see prescribing information. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections. Rx ONLY Distributed by Hospira, Inc., Lake Forest, IL 60045 USA (01) 103.04.09523.90.15
CO1)10304095239015

PRINCIPAL DISPLAY PANEL -2 g/50 mL Bag Pouch Label - 0409-5239

50 mL NDC 0409-5239-01

Magnesium Sulfate

in Water for Injection 2 g/50 mL (40 mg/mL)

2 g TOTAL

Each 50 mL contains magnesium sulfate heptahydrate 2 g (equivalent to 16.25 mEq magnesium) in water for injection. May contain sulfuric acid and/or sodium hydroxide for pH adjustment.

325 mOsmol/Liter (CALC.) pH 4.5 (3.5 to 6.5)

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER

POSSIBLE USE CENTRAL ROUTE.

Single-dose container. For intravenous use. Recommended dosage: See prescribing information. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See prescribing information.

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Rx ONLY

7 OTHER

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Hospira

13092-01



PRINCIPAL DISPLAY PANEL - 2 g/50 mL Bag Overwrap Back

Magnesium Sulfate

in Water for Injection 2 g/50 mL (40 mg/mL) 2 g TOTAL

13091-01



Ρ	roduct Infor	mation					
Pı	roduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)) NDC:	0409-6730
Ro	oute of Admini	stration	INTRAVENOUS				
Λ.	ctive Ingredi	ont/Activo	Mojety				
~	cuve mgreui		dient Name		Basis of S	trenath	Strengt
	AGNESIUM SULF TION - UNII:T6V3L	ATE HEPTAHY	(DRATE (UNII: SK47B8698T) (N	MAGNESIUM	MAGNESIUM SU HEPTAHYDRATE	JLFATE	80 mg in 1 mL
In	active Ingre						
			Ingredient Name			Stre	ength
	ATER (UNII: 059Q	F0KO0R)					
			RE)				
	ULFURIC ACID (U DIUM HYDROXI						
sc							
sc Pa	DIUM HYDROXI	DE (UNII: 55X04		Mark	eting Start Date		eting End Date
sc Pa #	ackaging	DE (UNII: 55X04	IQC32I)	Mark 03/31/20	Date		Date
sc Pa #	ackaging item Code NDC:0409-6730- 13	Pa 24 in 1 CASE 1 in 1 POUCH	QC32I) ckage Description	03/31/20	Date	Γ	Date
sc Pa # 1	ackaging Item Code NDC:0409-6730-	Pa 24 in 1 CASE 1 in 1 POUCH	IQC32I)	03/31/20	Date	Γ	Date
sc Pa # 1	ackaging Item Code NDC:0409-6730- 13 NDC:0409-6730-	Pa 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA	QC32I) ckage Description	03/31/20	Date 06	Γ	Date
SC Pa # 1 1 2 2	ACKaging Item Code NDC:0409-6730- 13 NDC:0409-6730- 11 NDC:0409-6730-	Pace 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product 60 in 1 CASE 1 in 1 POUCH	QC32I) ckage Description	03/31/20 12/27/20	Date 06	Γ	Date
SC Pa # 1 1 2 2	ACKaging Item Code NDC:0409-6730- 13 NDC:0409-6730- 11 NDC:0409-6730- 60 NDC:0409-6730-	Pa 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA	QC32I) ckage Description G; Type 0: Not a Combination	03/31/20 12/27/20	Date 06	Γ	Date
SC # 1 1 2 2 2	ACKaging Item Code NDC:0409-6730- 13 NDC:0409-6730- 11 NDC:0409-6730- 60 NDC:0409-6730-	Pace 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	QC32I) ckage Description G; Type 0: Not a Combination G; Type 0: Not a Combination	03/31/20 12/27/20	Date 06	Γ	Date
SC P 1 1 2 2 2	ACKaging Item Code NDC:0409-6730- 13 NDC:0409-6730- 11 NDC:0409-6730- 60 NDC:0409-6730- 50	Pac 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	QC32I) ckage Description G; Type 0: Not a Combination G; Type 0: Not a Combination	12/27/20	Date 06	Mark	Date

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0409-6729 Route of Administration INTRAVENOUS Basis of Strength Strength Active Ingredient/Active Moiety Basis of Strength Strength Strength Magnesium SULFATE HEPTAHYDRATE (UNII: SK47B8699T) (MAGNESIUM SULFATE (Magnesium SULFATE HEPTAHYDRATE (UNII: SK47B8699T) (MAGNESIUM SULFATE (Magnesium Source) Magnesium Sulfate (Magnesium Sulfate (Magnesium Source) 40 mg (in 1 ml Ingredient Name Strength Magnesium Sulfate (UNII: 0590F0K00R) Magnesium Sulfate (UNIII: 0590F0K00R) Strength Source (UNIII: 04000F0K0CP) Strength Source (UNIII: 04000F0K0CP) Source (UNIII: 04000F0K0CP) Source (UNIII: 04000F0K0CP) Source (UNIII: 04000F0K0CP) In 1 CASE 10/13/2005 In 1 POUCH OUC:0409-6729- 03 2 // 1 / 2 // 2 // 2 // 2 // 2 // 2 //								
Route of Administration INTRAVENOUS Active Ingredient/Active Moiety Basis of Strength Strength MACNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM MAGNESIUM SULFATE Of mg Inactive Ingredients Machaenee Strength Inactive Ingredients Ingredient Name Machaenee Strength Inactive Ingredients Ingredient Name Strength WATER (UNII: 0590F0K00R) Sobility Strength Sobility Ingredients Ingredient Name Machaenee Strength WATER (UNII: 0590F0K00R) Strength Machaenee Ingredient Name WATER (UNII: 0590F0K00R) Strength Machaenee Ingredient Name Strength Packaging Ingredient Name Marketing Start Marketing End Date 1 NDC:0409-6729- 24 in 1 CASE 10/13/2005 24 1 Product 2 NDC:0409-6729- 24 in 1 CASE 09/22/2005 02/01/2024 2 3 NDC:0409-6729- 24 in 1 CASE 09/28/2005 24 1 1 2 4 NDC:0409-6729- 100 mL in 1 BAG; Type 0: Not a Co			mation					
Active Ingredient/Active Molety ingredient Name Basis of Strength Strength MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK4788698T) (MAGNESIUM MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK4788698T) (MAGNESIUM HEPTAHYDRATE 1 n n n n n n n n n n n n n n n n n n					ltem (Code (Source)	NDC:0	0409-6729
Ingredient Name Basis of Strength Strength MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM MAGNESIUM SULFATE 40 mg in 1 mL CATION - UNII: TGV3LHY838) Ingredient S Strength Inactive Ingredients Strength Strength Inactive Ingredients Strength Strength WATER (UNII: 0590F0KOR) Strength Strength SULFURIC ACID (UNII: 55X04QC32I) Strength Marketing Start Packaging In 1 CASE 10/13/2005 Strength 1 MDC:0409-6729 24 in 1 CASE 10/13/2005 Strength 1 MC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 1 MD:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 2 ND:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 2 ND:0409-6729 24 in 1 CASE 09/28/2005 Strength 3 ND:0409-6729 10 mUCH In 1 POUCH In 1 POUCH 3 ND:0409-6729 12 in 1 CASE 09/28/2005 In 1 POUCH 3 ND:0409-6729 10 in PUUCH In 1 PUUCH In	R	oute of Admini	stration	INTRAVENOUS				
MacANESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM MECNESIUM SULFATE METAHYDRATE MacNESIUM SULFATE METAHYDRATE 40 mg in 1 mL Indextine Ingredient Name Strength Marketing Start Date 100 mL in 1 ASG; Type 0: Not a Combination 41 NDC:0409-6729 24 in 1 CASE 00 mL in 1 BAG; Type 0: Not a Combination 21 NDC:0409-6729 24 in 1 CASE 00 mL in 1 BAG; Type 0: Not a Combination 21 20:0409-6729 24 in 1 CASE 00 mL in 1 BAG; Type 0: Not a Combination 21 20:0409-6729 24 in 1 CASE 100 mL in 1 BAG; Type 0: Not a Combination 21 20:0409-6729	A	ctive Ingredi	ent/Active	Moiety				
CATION - UNII:T6V3LHY838) HEPTAHYDRATE In 1 mL In 1 mL Ingredient Name Strength Strength Strength Strength Strength Strength Strength Marketing Start Date Marketing Start Date Marketing End Date NDC:0409-6729 24 in 1 CASE 10/13/2005 O2/01/2024 I NDC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 I NDC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 I In 1 POUCH O2/01/2024 2 NDC:0409-6729 24 in 1 CASE 09/28/2005 02/01/2024 I In 1 POUCH O2/01/2024 2 NDC:0409-6729 20 1000 mL in 1 BAG; Type 0: Not a Combination Product In 1 CASE 09/28/2005 I I I <td></td> <td></td> <td>-</td> <td></td> <td></td> <td>Basis of S</td> <td>trength</td> <td>Strengt</td>			-			Basis of S	trength	Strengt
Ingredient Name Strength WATER (UNII: 059QF0K00R) SULFURIC ACID (UNI: 040UQP6WCF) SODIUM HYDROXIDE (UNII: 55X04QC32I) Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:0409-6729- 24 24 in 1 CASE 10/13/2005 02/01/2024 2 NDC:0409-6729- 03 24 in 1 CASE 08/22/2005 02/01/2024 2 NDC:0409-6729- 03 24 in 1 CASE 08/22/2005 02/01/2024 3 NDC:0409-6729- 09 20 in 1 BAG; Type 0: Not a Combination Product 09/28/2005 02/01/2024 3 NDC:0409-6729- 90 100 mL in 1 BAG; Type 0: Not a Combination Product 09/28/2005 02/01/2024 4 In 1 POUCH 11 11 POUCH 11 11 3 NDC:0409-6729- 9 12 in 1 CASE 09/28/2005 0 0 4 In 1 POUCH 11 11 DUCH 11/21/2006 11/21/2006 11/21/2006 11/21/2006 4 In 1 POUCH 11 in 1 POUCH 11 in 1 POUCH 11/21/2006 11/21/2006				DRATE (UNII: SK47B8698T) (MAGN	NESIUM		LFATE	5
WATER (UNII: 059QF0K00R) Marketing Start Marketing End Date SULFURIC ACID (UNII: 55X04QC32I) Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 200:0409-6729- 24 in 1 CASE 10/13/2005 0 1 NDC:0409-6729- 100 mL in 1 BAG; Type 0: Not a Combination Product 08/22/2005 02/01/2024 2 Dic:0409-6729- 21 24 in 1 CASE 09/28/2005 02/01/2024 3 NDC:0409-6729- 21 20 in 1 CASE 09/28/2005 02/01/2024 3 NDC:0409-6729- 21 100 mL in 1 BAG; Type 0: Not a Combination Product 0 0 3 NDC:0409-6729- 21 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 3 NDC:0409-6729- 21 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729- 24 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729- 24 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729- 24 100 mL in 1 BAG; Type 0: Not a Combination Product 0 0	11	nactive Ingre	dients					
SULFURIC ACID (UNII: 040UQP6WCF) SODIUM HYDROXIDE (UNII: 55X04QC32I) Marketing Start Date # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:0409-6729 24 in 1 CASE 10/13/2005 1 1 NDC:0409-6729 24 in 1 CASE 10/13/2005 2 2 NDC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 2 NDC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 2 NDC:0409-6729 500 mL in 1 BAG; Type 0: Not a Combination Product 0 2 NDC:0409-6729 500 mL in 1 BAG; Type 0: Not a Combination Product 09/28/2005 2 3 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 3 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 0 0 4 NDC:0409-6729 24 in 1 CASE <td< td=""><td></td><td></td><td></td><td>Ingredient Name</td><td></td><td></td><td>Stre</td><td>ngth</td></td<>				Ingredient Name			Stre	ngth
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Item Code Package Description Date Date NDC:0409-6729 24 in 1 CASE 10/13/2005 10/13/2005 NDC:0409-6729 10 mL in 1 BAG; Type 0: Not a Combination Product Image: Not in 1 BAG; Type 0: Not a Combination Product 08/22/2005 02/01/2024 NDC:0409-6729 24 in 1 CASE 08/22/2005 02/01/2024 NDC:0409-6729 500 mL in 1 BAG; Type 0: Not a Combination Product 09/28/2005 02/01/2024 NDC:0409-6729 12 in 1 CASE 09/28/2005 01 1 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 11/121/2006 11 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 11/21/2006 11 NDC:0409-6729 24 in 1 CASE 11/21/2006 11 11 NDC:0409-6729 24 in 1 CASE 11/21/2006 11 11 NDC:0409-6729 24 in 1 CASE 11/21/2006 11 11 NDC:0409-6729 1000 mL in 1 BAG; Type 0: Not a Combination Product 11 11 11	P	ackaging						
23 24 III 1 CASE 10/13/2003 1 1 in 1 POUCH 40 1 NDC:0409-6729- 100 mL in 1 BAG; Type 0: Not a Combination 08/22/2005 02/01/2024 2 NDC:0409-6729- 24 in 1 CASE 08/22/2005 02/01/2024 2 1 in 1 POUCH 68/22/2005 02/01/2024 2 1 in 1 POUCH 68/22/2005 02/01/2024 3 NDC:0409-6729- 500 mL in 1 BAG; Type 0: Not a Combination Product 99/28/2005 3 NDC:0409-6729- 12 in 1 CASE 09/28/2005 66/2000 3 NDC:0409-6729- 1000 mL in 1 BAG; Type 0: Not a Combination Product 11/21/2006 66/2000 4 NDC:0409-6729- 24 in 1 CASE 11/21/2006 66/2000 66/2000 4 NDC:0409-6729- 24 in 1 CASE 11/21/2006 66/2000 66/2000 4 NDC:0409-6729- 24 in 1 CASE 11/21/2006 66/2000 66/2000 4 NDC:0409-6729- 50 mL in 1 BAG; Type 0: Not a Combination Product 66/2000 66/2000 66/2000 4 NDC:0409-6729- 50 mL in 1 BAG; Type 0: Not a Combination Product	#	ltem Code	Pa	ckage Description	Mark			-
1NDC:0409-6729 41100 mL in 1 BAG; Type 0: Not a Combination Product08/22/200502/01/20242NDC:0409-6729 211 in 1 POUCHImage: Comparison of the comparison of	1		24 in 1 CASE		10/13/2	005		
41 Product Product OB Product Product 2 NDC:0409-6729- 21 24 in 1 CASE OB/22/2005 O2/01/2024 2 In 1 POUCH In 1 POUCH Product Product 3 NDC:0409-6729- 21 20 in 1 CASE O9/28/2005 Product Product 3 NDC:0409-6729- 90 12 in 1 CASE O9/28/2005 Product Product 3 NDC:0409-6729- 91 1000 mL in 1 BAG; Type 0: Not a Combination Product Product Product 4 NDC:0409-6729- 31 1000 mL in 1 CASE 11/21/2006 Product Product 4 NDC:0409-6729- 24 24 in 1 CASE 11/21/2006 Product Product 4 NDC:0409-6729- 24 50 mL in 1 BAG; Type 0: Not a Combination Product Product Product Product 4 NDC:0409-6729- 50 mL in 1 BAG; Type 0: Not a Combination Product Product Product Product	1		1 in 1 POUCH					
20324 IN 1 CASE08/22/200302/01/202421 in 1 POUCH2000 mL in 1 BAG; Type 0: Not a Combination Product09/28/200509/28/20053NDC:0409-6729- 0912 in 1 CASE09/28/200509/28/20053NDC:0409-6729- 311000 mL in 1 BAG; Type 0: Not a Combination Product11/21/200609/28/20054NDC:0409-6729- 2424 in 1 CASE11/21/200611/21/20064NDC:0409-6729- 2450 mL in 1 BAG; Type 0: Not a Combination Product11/21/200611/21/20064NDC:0409-6729- 2450 mL in 1 BAG; Type 0: Not a Combination Product11/21/200611/21/20065Som Lin 1 BAG; Type 0: Not a Combination Product11/21/200611/21/20064NDC:0409-6729- 50 mL in 1 BAG; Type 0: Not a Combination ProductMarketingMarketing Marketing StartMarketing End	1			AG; Type 0: Not a Combination				
2NDC:0409-6729- 21500 mL in 1 BAG; Type 0: Not a Combination Product09/28/20053NDC:0409-6729- 0912 in 1 CASE09/28/200531 in 1 POUCH1000 mL in 1 BAG; Type 0: Not a Combination Product11/21/20064NDC:0409-6729- 2424 in 1 CASE11/21/20064NDC:0409-6729- 50 mL in 1 BAG; Type 0: Not a Combination Product11/21/20064NDC:0409-6729- 2450 mL in 1 BAG; Type 0: Not a Combination Product11/21/200650Marketing InformationMarketing StartMarketing End								
2 21 Product Pr	2		24 in 1 CASE		08/22/2	005	02/01/202	4
3 09 12 IN 1 CASE 09/28/2005 3 1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination 1000 mL in 1 BAG; Type 0: Not a Combination 4 NDC:0409-6729- 24 24 in 1 CASE 11/21/2006 4 1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination 11/21/2006 4 NDC:0409-6729- 24 50 mL in 1 BAG; Type 0: Not a Combination 11/21/2006 4 NDC:0409-6729- 11 50 mL in 1 BAG; Type 0: Not a Combination 11/21/2006 50 mL in 1 BAG; Type 0: Not a Combination 11/21/2006 11/21/2006	2	03	1 in 1 POUCH	AG: Type 0: Not a Combination	08/22/2	005	02/01/202	4
3 NDC:0409-6729- 31 1000 mL in 1 BAG; Type 0: Not a Combination Product 11/21/2006 4 NDC:0409-6729- 24 24 in 1 CASE 11/21/2006 4 1 in 1 POUCH Image: Comparison of the temperature of temperatur	2	03 NDC:0409-6729- 21	1 in 1 POUCH 500 mL in 1 B/	AG; Type 0: Not a Combination	08/22/2	005	02/01/202	4
31 Product Image: Addition of the second of the secon	2 2	03 NDC:0409-6729- 21 NDC:0409-6729-	1 in 1 POUCH 500 mL in 1 B Product	AG; Type 0: Not a Combination			02/01/202	4
4 24 24 111 CASE 11/21/2000 4 1 in 1 POUCH 4 NDC:0409-6729- 11 50 mL in 1 BAG; Type 0: Not a Combination Product Marketing Information Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3	03 NDC:0409-6729- 21 NDC:0409-6729- 09	1 in 1 POUCH 500 mL in 1 B, Product 12 in 1 CASE 1 in 1 POUCH				02/01/202	4
4 NDC:0409-6729- 11 50 mL in 1 BAG; Type 0: Not a Combination Product Marketing Information Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3 3	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729-	1 in 1 POUCH 500 mL in 1 B, Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 B				02/01/202	4
4 11 Product Marketing Information Marketing Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3 3 3	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729- 31 NDC:0409-6729-	1 in 1 POUCH 500 mL in 1 B/ Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 B/ Product		09/28/2	005	02/01/202	4
Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3 3 4	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729- 31 NDC:0409-6729- 24	1 in 1 POUCH 500 mL in 1 BA Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 B Product 24 in 1 CASE 1 in 1 POUCH	BAG; Type 0: Not a Combination	09/28/2	005	02/01/202	4
Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3 3 4 4	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729- 31 NDC:0409-6729- 24 NDC:0409-6729-	1 in 1 POUCH 500 mL in 1 BA Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 BA Product 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA	BAG; Type 0: Not a Combination	09/28/2	005	02/01/202	4
Marketing Application Number or Monograph Marketing Start Marketing End	2 2 3 3 4 4	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729- 31 NDC:0409-6729- 24 NDC:0409-6729-	1 in 1 POUCH 500 mL in 1 BA Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 BA Product 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA	BAG; Type 0: Not a Combination	09/28/2	005	02/01/202	4
	2 3 3 4 4 4	03 NDC:0409-6729- 21 NDC:0409-6729- 09 NDC:0409-6729- 31 NDC:0409-6729- 24 NDC:0409-6729- 11	1 in 1 POUCH 500 mL in 1 BA Product 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 BA Product 24 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	BAG; Type 0: Not a Combination G; Type 0: Not a Combination	09/28/2	005		4

MAGNESIUM SULFATE IN WATER

magnesium sulfate in water injection, solution

Product Information

P	roduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source) NDC:0	0409-4121
R	oute of Admini	stration	INTRAVENOUS				
A	ctive Ingredi		•				
		-	dient Name		Basis of S	Strength	Strength
	AGNESIUM SULF TION - UNII:T6V3L		DRATE (UNII: SK47B8698T) (MAGN	IESIUM	MAGNESIUM SU HEPTAHYDRATE		4 g in 100 mL
		,					
In	active Ingre	dients					
			Ingredient Name			Stre	ngth
w	ATER (UNII: 059Q	F0KO0R)					
รเ	JLFURIC ACID (U	NII: O40UQP6W	CF)				
sc	DDIUM HYDROXI	DE (UNII: 55X04	4QC32I)				
Pa	ackaging						
#	ltem Code	Pa	ckage Description	Mark	ceting Start Date		ting End ate
1	NDC:0409-4121- 50	50 in 1 CASE		12/27/2	022		
1		1 in 1 POUCH					
1	NDC:0409-4121- 01	100 mL in 1 B Product	AG; Type 0: Not a Combination				
Μ	larketing	Informat	ion				
	Marketing Category	Applica	tion Number or Monograph Citation	Ma	rketing Start Date		eting End Date
NC	A	NDA020309		12/27	/2022		

MAGNESIUM SULFA magnesium sulfate in water in					
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:0	409-2050
Route of Administration	INTRAVENOUS				
Active Ingredient/Active	Moiety				
Ingre	dient Name		Basis of Stre	ngth	Strength
MAGNESIUM SULFATE HEPTAHY CATION - UNII:T6V3LHY838)	(DRATE (UNII: SK47B8698T) (MAGN	ESIUM	MAGNESIUM SULFA HEPTAHYDRATE	ГЕ	20 g in 500 mL
Inactive Ingredients					
	Ingredient Name			Stre	ngth
WATER (UNII: 059QF0K00R)					
SULFURIC ACID (UNII: O40UQP6V	VCF)				
SODIUM HYDROXIDE (UNII: 55X0	4QC32I)				

Pa	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-2050- 20	20 in 1 CASE	11/14/2022	
1		1 in 1 POUCH		
1	NDC:0409-2050- 01	500 mL in 1 BAG; Type 0: Not a Combination Product		
Μ	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NE	A	NDA020309	11/14/2022	

1 1 1	NDC:0409-3164- 01	Product	BAG; Type 0: Not a Combination				
1		1000 mL in 1 f	BAG; Type 0: Not a Combination				
_		1 in 1 POUCH					
1							
	NDC:0409-3164- 12	12 in 1 CASE		06/19/2	2023		
#	Item Code	Pa	ckage Description	Mar	keting Start Date		eting End Date
P	ackaging						
	JLFURIC ACID (U DDIUM HYDROXI						
	ATER (UNII: 059Q	•					
			Ingredient Name			Stre	ength
Ir	active Ingre	dients					
	TION - UNII:T6V3L				HEPTAHYDRATE		in 1000 m
м	AGNESIUM SULF	•	tient Name (DRATE (UNII: SK47B8698T) (MAGN	IESIUM	Basis of St MAGNESIUM SUL	-	Strengtl
A	ctive Ingredi						
R	oute of Admini	stration	INTRAVENOUS				
Ρ	roduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:	0409-3164
	roduct Infor	mation					
Ρ							
	agires lant s and		ijection, solution				

MAGNESIUM SULFATE IN WATER

magnesium sulfate in water injection, solution

P	roduct Infor	mation					
Pr	oduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source) NDC:	0409-5239
Ro	oute of Admini	stration	INTRAVENOUS				
	tivo Incuradi		Malah				
A	tive Ingredi		•				
		-	dient Name		Basis of S	-	Strengt
	GNESIUM SULF TION - UNII:T6V3L		DRATE (UNII: SK47B8698T) (MAG	NESIUM	MAGNESIUM SU HEPTAHYDRATE		2 g in 50 mL
In	active Ingre	dients					
			Ingredient Name			Stre	ngth
w	ATER (UNII: 059Q	F0KO0R)					
	LFURIC ACID (U		CF)				
SU		NII: O40UQP6W	,				
su so	LFURIC ACID (U DIUM HYDROXI	NII: O40UQP6W	,				
su so	LFURIC ACID (U	NII: O40UQP6W	,				
su so	LFURIC ACID (U DIUM HYDROXI	NII: 040UQP6W DE (UNII: 55X04	,	Mark	eting Start Date		ting End Pate
su so Pa #	LFURIC ACID (U DIUM HYDROXII	NII: 040UQP6W DE (UNII: 55X04	IQC32I)	Mark 12/27/20	Date		
su so Pa #	LFURIC ACID (U DIUM HYDROXII Ackaging Item Code NDC:0409-5239-	NII: 040UQP6W DE (UNII: 55X04 Pac	IQC32I)		Date		
SU SO Pa # 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 60	NII: 040UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH	IQC32I)		Date		
SU SO Pa # 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 60	NII: O40UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA	QC32I) ckage Description		Date		
su so # 1 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 60 NDC:0409-5239- 01	NII: O40UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	(QC32I) Ckage Description G; Type 0: Not a Combination		Date		
su so # 1 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 60	NII: O40UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	(QC32I) Ckage Description G; Type 0: Not a Combination		Date		
su so # 1 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 60 NDC:0409-5239- 01	NII: O40UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	(QC32I) Ckage Description G; Type 0: Not a Combination	12/27/20	Date	: Marke	
su so # 1 1	LFURIC ACID (U DIUM HYDROXII ackaging Item Code NDC:0409-5239- 01 NDC:0409-5239- 01 arketing Category	NII: O40UQP6W DE (UNII: 55X04 Pac 60 in 1 CASE 1 in 1 POUCH 50 mL in 1 BA Product	(QC32I) Ckage Description G; Type 0: Not a Combination ion tion Number or Monograph	12/27/20	Date 122 rketing Start	: Marke	eting End

Labeler - Hospira, Inc. (141588017)

Establishment			
Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-6729, 0409-6730) , MANUFACTURE(0409-6729, 0409-6730) , PACK(0409-6729, 0409-6730) , LABEL(0409-6729, 0409-6730)

Revised: 10/2023

Hospira, Inc.