Magnesium sulfate heptahydrate 50%   WHOPAR part 5   January 2018
Solution for Injection (2 ml)   Suppliers submission   update March 2019
(Martindale Pharma) RH073

PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON

1.   NAME OF THE MEDICINAL PRODUCT

Magnesium Sulfate 50% w/v Solution for Injection

2.   STATEMENT OF ACTIVE SUBSTANCE(S)

Magnesium Sulfate (heptahydrate) 50% w/v

2ml contains 4mmol of Magnesium and Sulfate ions (2mmol/ml).

5ml contains 10mmol of Magnesium and Sulfate ions (2mmol/ml).

10ml contains 20mmol of Magnesium and Sulfate ions (2mmol/ml)

3.   LIST OF EXCIPIENTS

Water for Injection.

It may also contain sodium hydroxide.

4.   PHARMACEUTICAL FORM AND CONTENTS

Solution for Injection

10 x 2ml ampoules

10 x 5ml ampoules

10 x 10ml ampoules

5.   METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Solution for IM injection. Concentrate for IV infusion.

Magnesium sulfate heptahydrate 50%
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6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

MUST BE DILUTED PRIOR TO IV INFUSION

8. EXPIRY DATE

Exp:

9. SPECIAL STORAGE CONDITIONS

Store below 25ºC

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

For single use only.

Discard any unused contents.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Marketing Authorisation Holder: Aurum Pharmaceuticals, Romford, Essex RM3 8UG, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 12064/0013

Magnesium sulfate heptahydrate 50%   WHOPAR part 5   January 2018
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13.   BATCH NUMBER<, DONATION AND PRODUCT CODES>

Lot:

14.   GENERAL CLASSIFICATION FOR SUPPLY

POM

15.   INSTRUCTIONS ON USE

Use as directed by the physician

16.   INFORMATION IN BRAILLE

N/A

17.   UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18.   UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

Magnesium sulfate heptahydrate 50%
Solution for Injection (2 ml)
(Martindale Pharma) RH073

WHOPAR part 5
Suppliers submission

January 2018
update March 2019

> **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LABEL**

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Magnesium Sulfate 50%w/v Solution for Injection

2mmol Mg^{2+}/ml

2. METHOD OF ADMINISTRATION

For IM injection. After dilution, for IV injection.

3. EXPIRY DATE

Exp:

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1g in 2ml
2.5g in 5ml
5g in 10ml

6. OTHER

Aurum Pharmaceuticals Ltd

PL 12064/0013

POM

Magnesium sulfate heptahydrate 50%
Solution for Injection (2 ml)
(Martindale Pharma) RH073

WHOPAR part 5
Suppliers submission

January 2018
update March 2019

GTIN (01) XXXXXXXXXXXXXXX
Batch (10) XXXXXX
Expiry (17) XXXXXX
Serial (21) XXXXXXXXXXXXXX

1g in **2ml** 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.
2ml contains 4 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.

MUST BE DILUTED PRIOR TO IV INFUSION

Marketed by Martindale Pharma, Romford, Essex RM3 8UG, UK.
Marketing Authorization Holder: Aurum Pharmaceuticals, Romford, Essex RM3 8UG, UK.
PL 12064/0013

10 x 2ml ampoules

Magnesium Sulphate Injection 50% w/v

4100595

10 x 2ml ampoules

Magnesium Sulfate 50%w/v
Solution for Injection

Solution for IM injection. Concentrate for IV infusion.

1g in **2ml** as the heptahydrate

5 026448 179121

1g in **2ml**
as the heptahydrate

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

Solution for IM injection
Concentrate for IV infusion
2ml contains 4 mmol of Magnesium and Sulfate ions (2 mmol/ml)

MUST BE DILUTED PRIOR TO IV INFUSION

POM

10 x 2ml ampoules

1g in 2ml as the heptahydrate

Magnesium Sulfate

1g in **2ml as the heptahydrate**

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

Solution for IM injection. Concentrate for IV infusion.

10 x 2ml ampoules