

**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.

**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 25°C

**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

**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]>

**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<sup>2+</sup>/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

