

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[RH086 trade name]*

Magnesium Sulfate Heptahydrate 500 mg/mL Solution for Injection

2. Statement of active substance

Each mL contains Magnesium Sulfate Heptahydrate 500 mg

3. List of excipients

0.5M solution of sulfuric acid and/or 0.1M solution of sodium hydroxide (for adjustment of pH)

Water for injections

See patient information leaflet for further information.

4. Pharmaceutical form and contents

A clear colourless solution.

10 ampoules of 10 mL

5. Method and route of administration

STERILE

For intravenous and intramuscular use.

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30 °C. Do not freeze.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the supplier

Joint Stock Company “Halychpharm”
6/8, Opryshkivska Str., Lviv, 79024, Ukraine

12. WHO Reference Number (Prequalification Programme)

RH086

13. Manufacturer’s batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Ampoule label

1. Name of the medicinal product

[RH086 trade name]*

Magnesium Sulfate Heptahydrate 500 mg/mL Solution for Injection

2. Method and route of administration

STERILE

IV or IM

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Content by Weight, by Volume or by Unit

10 mL