

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton Box

1. NAME OF THE MEDICINAL PRODUCT

Magnesiumsulfat 50% Inresa

2. STATEMENT OF ACTIVE SUBSTANCES

One 10 mL ampoule contains:

Active substance: 5.0 g magnesium sulphate heptahydrate equivalent to 493 mg magnesium ions
(equivalent to 20.25 mmol Mg)

3. LIST OF EXCIPIENTS

Other ingredients:

Water for injections, sulphuric acid 95-98% for pH adjustment

4. PHARMACEUTICAL FORM AND CONTENTS

Concentrate for solution for injection or infusion

10 ampoules, each with 10 mL

10 ampoules, each with 10 mL concentrate for solution for injection or infusion

5. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

For intravenous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep this medicine out of the sight and reach of children.

7. OTHER SPECIAL WARNINGS IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

11. NAME AND ADDRESS OF APPLICANT/SUPPLIER

Inresa Arzneimittel GmbH
Obere Hardtstraße 18
79114 Freiburg
Tel.: 0761 / 475047
Fax: 0761 / 475127
E-Mail: info@inresa.com

12. AUTHORISATION NUMBER(S)

MA no: 6914444.00.00

13. BATCH NUMBER

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MINIMUM PARTICULAR TO APPEAR ON SMALL IMMEDIATE PACKING UNITS
Label for ampoule

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

Magnesiumsulfat 50% Inresa

Concentrate for solution for injection/infusion

1 ampoule (10 mL) contains: 5.0 g magnesium sulphate heptahydrate for i.v. use

2. METHOD OF ADMINISTRATION

Do not store above 25°C.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, VOLUME OR BY UNIT

2 mmol Mg/ml

6. OTHER

Inresa Arzneimittel GmbH