

LABELING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label/Glass ampoules

1. NAME OF THE MEDICINAL PRODUCT

Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP*

2. STATEMENT OF ACTIVE SUBSTANCE

1 ampoule (2 ml) contains 1000 mg of magnesium sulfate heptahydrate.
The concentration of magnesium ions is approximately 2 mmol per ml.

3. LIST OF EXCIPIENTS

0.1 M solution of sulfuric acid/0.1 M solution of sodium hydroxide (for adjustment of pH), water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

10 ampoules of 2 ml
100 ampoules of 2 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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Do not freeze.
Single use ampoules. Discard unused portion.

**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

AS KALCEKS
Krustpils iela 71E
Riga, LV-1057
Latvia

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

RH063

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON AMPOULE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP[†]

2. METHOD OF ADMINISTRATION

STERILE
i.v., i.m.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2 ml

6. OTHER

<Logo>

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