

## **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 (10 ml) contains 5000 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

5 ampoules of 10 ml  
10 ampoules of 10 ml  
100 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 SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

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

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**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)**

RH064

**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<sup>†</sup>

**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**

10 ml

**6. OTHER**

<Logo>

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