

**DIRECTIONS TO BE INCLUDED IN SECONDARY PACKAGING MATERIAL**

**CARD BOXES**

**1. NAME OF THE MEDICINAL PRODUCT**

Magnesium Sulphate Labesfal, 5000 mg/10 ml, solution for injection

Magnesium sulphate heptahydrate

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

**Composition:**

Each ml of solution for injection contains 500 mg of magnesium sulphate heptahydrate

**3. LIST OF EXCIPIENTS**

Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for injection

6 ampoules of 10 ml < to be included in the package of 6 ampoules of 10 ml >  
12 ampoules of 10 ml < to be included in the package of 12 ampoules of 10 ml >  
50 ampoules of 10 ml < to be included in the package of 50 ampoules of 10 ml >  
100 ampoules of 10 ml < to be included in the package of 100 ampoules of 10 ml >

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use

Intramuscular and intravenous use (previously diluted)

<space for the registration of the prescribed dosage>

**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**

Contains  $\approx$  2 mmol/ml or 4 mEq/ml of Mg.

**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**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Labesfal – Laboratórios Almiro, S.A.  
Zona Industrial do Lagedo  
3465-157 Santiago de Besteiros  
Portugal

**12. MARKETING AUTHORISATION NUMBER(S)**

Registration n.º 3259397 on INFARMED, I.P. < to be included in the package of 6 ampoules of 10 ml >  
Registration n.º 3259496 on INFARMED, I.P. < to be included in the package of 12 ampoules of 10 ml >  
Registration n.º 3259595 on INFARMED, I.P. < to be included in the package of 50 ampoules of 10 ml >  
Registration n.º 3259694 on INFARMED, I.P. < to be included in the package of 100 ampoules of 10 ml >

POP, if applicable and in accordance with the criteria and legislation in force.

**13. BATCH NUMBER**

Batch

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**MINIMUM DIRECTIONS TO BE INCLUDED IN SMALL UNITS OF PRIMARY PACKAGING**

**AMPOULES**

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

Magnesium Sulphate Labesfal, 5000 mg/10 ml, solution for injection

Magnesium sulphate heptahydrate

**I.M./I.V. (previously diluted)**

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

Exp.

**4. BATCH NUMBER**

Batch

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

10 ml

**6. OTHER**

LABESFAL