

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**10 x 500 ml LDPE bottles**  
**10 x 1000 ml LDPE bottles**

### **1. NAME OF THE MEDICINAL PRODUCT**

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion

Potassium Chloride/Sodium Chloride

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

Each ml contains 1.50 mg Potassium Chloride and 9.00 mg Sodium Chloride.

Electrolytes per 500 ml:

K<sup>+</sup>: 10 mmol

Na<sup>+</sup>: 77 mmol

Cl<sup>-</sup>: 87 mmol

Electrolytes per 1000 ml:

K<sup>+</sup>: 20 mmol

Na<sup>+</sup>: 154 mmol

Cl<sup>-</sup>: 174 mmol

$\frac{10 \text{ mmol K}^+}{500 \text{ ml}}$

$\frac{20 \text{ mmol K}^+}{1000 \text{ ml}}$

Osmolarity: 348 mOsm/l (approx.)

pH: 4.5 – 7.0

### **3. LIST OF EXCIPIENTS**

Water for injections, sodium hydroxide, hydrochloric acid

### **4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for infusion

10 x 500 ml

10 x 1000 ml

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

Intravenous use.

Ready to use solution.

For single use only.  
Discard any unused solution.  
Read the package 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**

Rapid infusion may be harmful.

**8. EXPIRY DATE**

EXP (MM/YYYY)  
After first opening the product should be used immediately.

**9. SPECIAL STORAGE CONDITIONS**

**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**

Fresenius Kabi

[To be completed nationally]

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

[To be completed nationally]

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

[To be completed nationally]

**15. INSTRUCTIONS ON USE**

[To be completed nationally]

## 16. INFORMATION IN BRAILLE

[Justification for not including Braille accepted.]