PARTICULARS TO APPEAR ON THE INNER PACKAGING

500 ml LDPE bottles
1000 ml LDPE bottles

1. NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v Solution for Infusion

Potassium Chloride/Sodium Chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml contains 3.00 mg Potassium Chloride and 9.00 mg Sodium Chloride.

Electrolytes per 500 ml:
K^+: 20 mmol
Na^+: 77 mmol
Cl^-: 97 mmol

Electrolytes per 1000 ml:
K^+: 40 mmol
Na^+: 154 mmol
Cl^-: 194 mmol

$\frac{20 \text{ mmol } K^+}{500 \text{ ml}}$

$\frac{40 \text{ mmol } K^+}{1000 \text{ ml}}$

Osmolarity: 388 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

500 ml
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

The statement on not including Braille has been accepted.