

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Outer carton**

( 5x 100 ml bag, 24 x 100 ml bag, 60 x 100 mg bag, 5 x 200 ml bag, 12 x 200 ml bag, 32 x 200 mg bag)

**1. NAME OF THE MEDICINAL PRODUCT**

Levobupivacaine Kabi 0.625 mg/ml solution for infusion

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

1 ml solution contains 0.625 mg levobupivacaine (as levobupivacaine hydrochloride).  
Each bag of 100 ml contains 62.5 mg levobupivacaine (as levobupivacaine hydrochloride).  
Each bag of 200 ml contains 125 mg levobupivacaine (as levobupivacaine hydrochloride).

**3. LIST OF EXCIPIENTS**

Water for injections, sodium chloride, sodium hydroxide, hydrochloric acid.

See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

solution for infusion

5 [24 or 60] x 100 ml

5 [12 or 32] x 200 ml

62.5 mg/100 ml

125 mg/200 ml

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

Epidural use.

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**

For single use only.

Discard any unused solution.

**8. EXPIRY DATE**

EXP (MM/YYYY)

After first opening : The product should be used immediately.

Read the leaflet for the shelf-life after dilution.

**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**

[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

**17. UNIQUE IDENTIFIER – 2D BARCODE**

<2D barcode carrying the unique identifier included.>

<Not applicable.>

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

< PC: {number} [product code]

SN: {number} [serial number]

NN: {number} [national reimbursement number or other national number identifying the medicinal product]>