

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]>