1.3.1.2 Labelling text

Enclosed in subsequent pages,

AMPOULE

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> {CARTON}

1. NAME OF THE MEDICINAL PRODUCT

<Invented name> 5 mg/ml solution for injection
Bupivacaine Hydrochloride Anhydrous

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 1ml solution contains 5 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)
Each 2ml solution contains 10 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)
Each 4ml solution contains 20 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)
Each 5ml solution contains 25 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)
Each 10ml solution contains 50 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, sodium hydroxide (E524) (for pH adjustment), water for injections.
Also contains sodium. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
10 X 2 ml ampoule
05 X 2 ml ampoule
10 X 4 ml ampoule
05 X 4 ml ampoule
10 X 5 ml ampoule
05 X 5 ml ampoule
20 X 10 ml ampoule
15 X 10 ml ampoule
10 X 10 ml ampoule
05 X 10 ml ampoule

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For Nerve block, Caudal, Epidural and Infiltration Anesthesia
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

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8. EXPIRY DATE

EXP

For single use only.
Use immediately after opening.

9. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused contents.

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

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16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

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

<Invented Name> 5 mg/ml solution for injection

Bupivacaine Hydrochloride Anhydrous
Nerve block, Caudal, Epidural and Infiltration Anesthesia

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 mg/ml
10 mg/2 ml
20 mg/4 ml
25 mg/5 ml
50 mg/10 ml

6. OTHER

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VIAL:

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> {CARTON}

1. NAME OF THE MEDICINAL PRODUCT

<Invented Name> 5 mg/ml solution for injection
Bupivacaine Hydrochloride Anhydrous

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 1ml solution contains 5 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)
Each 20ml solution contains 100 mg bupivacaine hydrochloride (as monohydrate) (5mg/ml)

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, sodium hydroxide (E524) (for pH adjustment), water for injections.
Also contains sodium. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
20 ml vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For Nerve block, Caudal, Epidural and Infiltration Anesthesia
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

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8. EXPIRY DATE

EXP

For single use only.
Use immediately after opening.

9. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused contents.

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

--

16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

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

<Invented Name> 5 mg/ml solution for injection

Bupivacaine Hydrochloride Anhydrous
Nerve block, Caudal, Epidural and Infiltration Anesthesia

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 mg/ml
100 mg/20 ml

6. OTHER

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