

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

[Nationally approved name] 100 micrograms/ml, concentrate for solution for infusion
dexmedetomidine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml of concentrate contains dexmedetomidine hydrochloride equivalent to 100 micrograms
dexmedetomidine.

3. LIST OF EXCIPIENTS

Sodium chloride, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Concentrate for solution for infusion

5 x 2 ml ampoules
25 x 2 ml ampoules
5 x 2 ml vials
4 x 4 ml vials
5 x 4 ml vials
4 x 10 ml vials
5 x 10 ml vials

200 micrograms/2 ml
400 micrograms/4 ml
1000 micrograms/10 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Dilute before use.
For intravenous use only
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

8. EXPIRY DATE

EXP

Read the leaflet for the shelf-life of the diluted medicine.

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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<, DONATION AND PRODUCT CODES>

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[to be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number}

SN: {number}

NN: {number} >

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL or AMPOULES

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

[Nationally approved name] 100 micrograms/ml, concentrate for solution for infusion
dexmedetomidine
IV

2. METHOD OF ADMINISTRATION

Dilute before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2 ml (200 micrograms/2ml)
4 ml (400 micrograms/4ml)
10 ml (1000 micrograms/10ml)

6. OTHER