

A. LABELLING¹

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Outer packaging

1. NAME OF THE MEDICINAL PRODUCT

Oxytocin 10 IU/ml Concentrate for solution for infusion
Oxytocin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ampoule of 1 ml of solution contains 10 IU (16,7 micrograms) of oxytocin

3. LIST OF EXCIPIENTS

Sodium chloride, glacial acetic acid, sodium acetate tri-hydrate, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Concentrate for solution for infusion
3 x1 ml ampoules / 5 x 1 ml ampoules / 10 x 1 ml ampoules.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use (infusion)
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

Not applicable.

8. EXPIRY DATE

EXP {MM/AAAA}

After reconstitution, immediate use is recommended, read the package leaflet before use.

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C). Keep the ampoules in the outer carton 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

MA Holder:
PANPHARMA
Z.I. DU CLAIRAY
35133 LUITRE
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

PL 44124/0024

13. BATCH NUMBER

Batch {Number}

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Not applicable

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
AMPOULE

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

Oxytocin 10 IU/ml Concentrate for solution for infusion
Intravenous use (infusion)

2. METHOD OF ADMINISTRATION

Not applicable

3. EXPIRY DATE

EXP {MM/AAAA}

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Batch {Number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Not applicable.

6. OTHER

Not applicable.