

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

[RH083 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each 1 ml ampoule contains 10 International Units oxytocin.

3. LIST OF EXCIPIENTS

This medicinal product contains ethanol, chlorobutanol, sodium acetate trihydrate, sodium chloride, glacial acetic acid and water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

5 ampoules per plastic ampoule tray
10 ampoules per plastic ampoule tray
100 ampoules per plastic ampoule tray

5. METHOD AND ROUTE OF ADMINISTRATION

For intravenous and intramuscular use.

Read the patient information leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE
STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C-8°C) in the original carton, protected from light. Do not freeze.

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 SUPPLIER

Steril-Gene Life Sciences (P) Ltd
No.15, Gopalakrishna Road
T. Nagar, Chennai-600 017
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

RH083

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

1. NAME OF THE MEDICINAL PRODUCT

[RH083 trade name]

2. NAME OF THE SUPPLIER

Steril-Gen Life Sciences (P) Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}