

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **Carton**

#### **1. Name of the medicinal product**

[RH083 trade name]\* Oxytocin 10 IU/mL Solution for Injection  
Oxytocin

#### **2. Statement of active substance**

Each 1 ml ampoule contains 10 IU 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 in a honey comb pack

#### **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}

#### **9. Special storage conditions**

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

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

**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> <Lot> {number}

**14. (Advice on) General classification for supply**

{Medicinal product subject to medical prescription.}

**15. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Clear Glass Ampoule USP Type I

**1. Name of the medicinal product and route(s) of administration**

[RH083 trade name] Oxytocin 10 IU Solution for Injection

Oxytocin

Parenteral

**2. Method of administration**

Intravenous and Intramuscular

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Contents by weight, by volume, or by unit**

International Unit

**6. Other**