

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

**1. NAME OF THE MEDICINAL PRODUCT**

Santocyn<sup>1</sup>

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each 1 ml ampoule contains 10 International Units oxytocin.

**3. LIST OF EXCIPIENTS**

This medicinal product contains: Chlorobutanol hemihydrate, glacial acetic acid, anhydrous sodium acetate, ethanol, sodium chloride and water for injection.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for injection  
5 × 2 ampoules

**5. METHOD AND ROUTE OF ADMINISTRATION**

For intravenous infusion.

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}

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

**9. SPECIAL STORAGE CONDITIONS**

Store the ampoules refrigerated (2–8°C) in the original cartons 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**

PT Sanbe Farma  
Jl. Taman Sari No.10, Bandung, 40116- Indonesia  
Tel: 62 22 4207725 (Hunting)  
Fax: 62 22 4238476

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

RH050

**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**

Santocyn 10 units/mL Solution for Injection  
Oxytocin

**2. NAME OF THE SUPPLIER**

PT Sanbe Farma

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

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