

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

{Carton Box}

1. NAME OF THE MEDICINAL PRODUCT

[RH079 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 chlorobutanol hemihydrate, acetic acid glacial and water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

5 ampoules per PVC film liner
10 ampoules per PVC film liner
100 ampoules per PVC film liner

5. METHOD AND ROUTE OF ADMINISTRATION

Sterile. 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). Do not freeze.
Single use ampoules. Discard unused portion.

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

AS GRINDEKS.
Krustpils iela 53, Rīga, LV-1057, Latvia

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

RH079

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

[RH079 trade name]

2. NAME OF THE SUPPLIER

JSC Grindeks

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 ml