

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton Box

1. Name of the medicinal product

[RH079 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

Contains chlorobutanol hemihydrate, acetic acid glacial and water for injections

4. Pharmaceutical form and contents

Solution for injection

5 ampoules

10 ampoules

100 ampoules

5. Method and route of administration

Sterile.

For intravenous or 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 this medicine out of the sight and reach 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). Do not freeze.

Single use ampoules. Discard unused portion.

* 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

JSC Grindeks
53 Krustpils Street,
Riga, LV-1057
Latvia

12. WHO Reference Number (Prequalification Programme)

RH079

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

Ampoule

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

[RH079 trade name] Oxytocin 10 IU/mL solution for injection

Oxytocin

2. Method of administration

Sterile.

i.v., i.m.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

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

1mL

6. Other

<Logo>