

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH090 trade name]*

Medroxyprogesterone acetate 150 mg/mL suspension for injection Sterile

2. Statement of active substance

Each mL of suspension contains 150 mg medroxyprogesterone acetate

3. List of excipients

Polyethylene glycol 3350, polysorbate 80, sodium chloride, methyl paraben, propyl paraben, sodium hydroxide, hydrochloric acid and water for injection.

4. Pharmaceutical form and contents

Suspension for injection
20 vials

5. Method and route of administration

For intramuscular use only
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 {MMM/YY}

9. Special storage conditions

Do not store above 30°C. Keep the glass vial in the provided carton to protect the product from light. Do not freeze. Vials must be stored upright. Avoid excursions above 30°C.

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 Tunggal Idaman Abdi
Jl. Jend. Ahmad Yani No.7

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

Jakarta 13230
Indonesia

12. WHO Reference Number (Prequalification Programme)

RH090

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

<To be decided by the national medicines regulatory authority in accordance with national legislation.>

15. Instructions on use

Shake the vial well just before use

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

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

[RH090 trade name]

Medroxyprogesterone acetate 150mg/mL suspension for injection

For intramuscular use only

Sterile

2. Method of administration

Shake the vial well just before use

3. Expiry date

EXP {MMM/YY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

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

1mL

6. Other