

## **LABELLING**

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

Outer carton

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

[RH090 trade name]\* Medroxyprogesterone acetate 150 mg/mL suspension for injection  
Medroxyprogesterone acetate

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

Each mL of suspension contains 150 mg medroxyprogesterone acetate

### **3. List of excipients**

Each mL of suspension contains about 1.351 mg of methyl paraben and 0.147 mg of propyl paraben.

See patient information leaflet for further information

### **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**

---

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

**11. Name and address of the supplier**

PT Tunggal Idaman Abdi  
Jl. Jend. Ahmad Yani No.7  
Jakarta 13230

**12. WHO Reference Number (Prequalification Programme)**

RH090

**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**

Shake vigorously immediately 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 150 mg/mL suspension for injection

Medroxyprogesterone acetate

For intramuscular use only

Sterile

**2. Method of administration**

Shake vigorously immediately 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**

1 mL

**6. Other**