

## **LABELLING**

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

Carton

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

[RH084 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 1.37 mg of methyl paraben and 0.15 mg of propyl paraben.

See patient information leaflet for further information

### **4. Pharmaceutical form and contents**

Sterile Suspension for injection

1 vial

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 {MM/YYYY}

### **9. Special storage conditions**

Do not store above 30°C. Do not freeze.

Store vials in the cartons to protect from light.

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\* 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**

Incepta Pharmaceuticals Ltd  
40, Shahid Tajuddin Ahmed Sarani  
Tejgaon I/A, Dhaka-1208  
Bangladesh

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

RH084

**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**

[RH084 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 {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

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

1 mL

**6. Other**