

## **LABELLING**

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

### **Carton**

**1. Name of the medicinal product**

[RH084 trade name]\*

**2. Statement of active substance**

150 mg medroxyprogesterone acetate

**3. List of excipients**

Polyethylene glycol 3350, polysorbate 80, sodium chloride (injectible grade), methyl paraben, propyl paraben, sodium hydroxide, hydrochloric acid 37%, nitrogen (injectable grade, for air displacement) and water for injection.

Read the patient information leaflet before use

**4. Pharmaceutical form and contents**

Suspension for injection

Sterile

1 vial in an inner carton

20 vials in an inner carton

**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 out of the reach and sight 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.

**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

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

**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]  
150 mg 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**