

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[RH074 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

Suspension for injection

25 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.

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

Senador Laboratories Private Limited
Plot 2B & 2C, Biotech Park
Phase II, Lalgadi Malakpet,
Medchal Malkajgiri
Hyderabad, Telangana
India, 500101.

12. WHO Reference Number (Prequalification Programme)

RH074

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

[RH074 trade name] medroxyprogesterone acetate 150 mg/mL suspension for injection

Medroxyprogesterone acetate

For intramuscular use only

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