

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH106 trade name]* Medroxyprogesterone acetate 104mg/0.65ml suspension for injection

Medroxyprogesterone acetate

2. Statement of active substance

Each 0.65mL contains 104mg of medroxyprogesterone acetate

3. List of excipients

Each 0.65mL contains about 1.04mg methyl paraben and 0.098mg propyl paraben
See patient information leaflet for further information

4. Pharmaceutical form and contents

Sterile Suspension for injection

1 uniject prefilled injection

100 uniject prefilled injections

5. Method and route of administration

For subcutaneous 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 refrigerate or freeze.

Store uniject pre filled syringes in the carton

* 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
Email: enquiry@inceptapharma.com

12. WHO Reference Number (Prequalification Programme)

RH106

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

See patient information leaflet

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium foil pouch

1. Name of the medicinal product

[RH106 trade name] Medroxyprogesterone acetate 104mg/0.65ml suspension for injection

Medroxyprogesterone acetate

2. Name of the supplier

Incepta Pharmaceuticals Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LDPE pre-filled injection (uniject)

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

[RH106 trade name] Medroxyprogesterone acetate 104mg/0.65ml suspension for injection

Medroxyprogesterone acetate

Subcutaneous injection

2. Method of administration

Subcutaneous injection

3. Expiry date

EXP: MM/YYYY

4. Manufacturer's batch number

<Batch> <Lot> {number}

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

Each 0.65mL contains 104 mg medroxyprogesterone acetate

6. Other