

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

(Carton)

1. NAME OF THE MEDICINAL PRODUCT

[RH074 trade name]¹
Sterile

2. STATEMENT OF ACTIVE SUBSTANCE

Each mL contains 150 mg medroxyprogesterone acetate

3. LIST OF EXCIPIENTS

Contains polysorbate 80, macrogol 3350, methyl paraben, propyl paraben, sodium chloride, water for injection, hydrochloric acid and/or sodium hydroxide.

Read the patient information leaflet before use

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for Injection

25 vials in 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

¹Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

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**

Shake vigorously immediately before use.
Medical product subject to medical prescription

11. NAME AND ADDRESS OF THE SUPPLIER

Mylan Laboratories Limited
Plot No. 20 & 21, Pharmez
The Pharmaceutical Special Economic Zone
Sarkhej – Bavla National Highway No. 8-A
Nr. Village – Matoda
Tal- Sanand
Dist. – Ahmedabad
Postal code: 382213
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

RH074

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (Vials)

1. NAME OF THE MEDICINAL PRODUCT

[RH074 trade name]
Sterile
Each mL contains medroxyprogesterone acetate, 150mg
For intramuscular use only

2. NAME OF THE SUPPLIER

Mylan Laboratories Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}