# **LABELLING**

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

### 1. Name of the medicinal product

[RH032 trade name]\* Levonorgestrel 750 micrograms tablets

#### 2. Statement of active substance

Each tablet contains 750 micrograms levonorgestrel

#### 3. List of excipients

The tablet also contains lactose monohydrate.

#### 4. Pharmaceutical form and contents

**Tablets** 

1 x 2 tablets

#### 5. Method and route of administration

Oral use.

Read the package 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. Protect from light. Store the tablets in the blister in provided carton.

# 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

Mylan Laboratories Limited Plot No.564/A/22, Road No.92, Jubilee Hills Hyderabad, Telangana – 500096, India

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

RH032

#### 13. Manufacturer's batch number

<Batch> <Lot> {number}

# 14. General classification for supply

Medicinal product subject to medical prescription

#### 15. Instructions on use

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

<sup>†</sup> Formerly Famy Care Ltd then Jai Pharma Ltd

## MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

# 1. Name of the medicinal product

[RH032 trade name] Levonorgestrel 750 micrograms tablets

## 2. Name of the supplier

Mylan Laboratories Limited

# 3. Expiry date

EXP {MM/YYYY}

## 4. Manufacturer's batch number

<Batch> <Lot>{number}

# 5. Other