## **LABELLING**

# PARTICULARS TO APPEAR ON THE OUTER PACKAGING HDPE bottle

### 1. Name of the medicinal product

[HA723 trade name]\* Darunavir 400 mg Tablets

### 2. Statement of active substance

Each tablet contains 400 mg darunavir.

### 3. List of excipients

#### 4. Pharmaceutical form and contents

Tablets

30 tablets.

#### 5. Method and route of administration

Oral use

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. Protect from light and moisture. Avoid excursions above 30°C.

# 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

MSN Laboratories Private Limited "MSN House", Plot No. C-24 Industrial Estate, Sanath Nagar Hyderabad, Telangana, 500 018, India

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

HA723

### 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

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

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