

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA723 trade name]* Darunavir 400 mg film-coated tablet
Darunavir

2. Statement of active substance

Each film-coated 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

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

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