

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[HA757 trade name]* darunavir (as ethanolate)/ ritonavir 400mg/50mg tablets

Darunavir/ritonavir

2. Statement of active substance

Each tablet contains 433.64 mg darunavir ethanolate equivalent to 400mg darunavir and 50mg ritonavir

3. List of excipients

Refer to product information

4. Pharmaceutical form and contents

Film-coated tablets

56 tablets

60 tablets

180 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. Avoid excursions above 30°C.

Discard the product 90 days after initial opening. (Applicable to 180's count HDPE bottles)

* 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

Hetero Labs Limited,
7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar, Hyderabad-500 018.
Telangana, India.

12. WHO Reference Number (Prequalification Programme)

HA757

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