

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[HA719 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

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

60 tablets

120 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 moisture.

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

Hetero Labs Limited

12. WHO Reference Number (Prequalification Programme)

HA719

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