

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE (plastic) Bottle

1. Name of the medicinal product

[HA709 trade name]* Darunavir 400mg film-coated tablets
Darunavir

2. Statement of active substance

Each film-coated tablet contains 400mg darunavir

3. List of excipients

Each film-coated tablet contains FD&C yellow #6/Sunset yellow FCF aluminium lake

4. Pharmaceutical form and contents

60 film-coated 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. Store in the original container.

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

Laurus Labs Limited
Plot No.103, Road No.1, Jubilee Hills,

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

Hyderabad – 500 033, Telangana,
India.

12. WHO Reference Number (Prequalification Programme)

HA709

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