

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label and carton

1. Name of the medicinal product

[HA627 trade name]¹ Darunavir (as ethanolate) 400 mg Tablets
Darunavir (as ethanolate)

2. Statement of active substance

Each film-coated tablet contains 400 mg Darunavir

3. List of excipients

Contains FD&C yellow #6/Sunset yellow FCF Aluminium Lake

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

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 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.

¹ 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

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel Mumbai: 400013
India.

12. WHO Reference Number (Prequalification Programme)

HA627

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