

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

Bottle and Carton

1. NAME OF THE MEDICINAL PRODUCT

Darunavir (as ethanolate) 600 mg Tablets*

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 600 mg darunavir

3. LIST OF EXCIPIENTS

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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

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

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

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA685

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE