

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE bottle**

- 1. Name of the medicinal product**
[HA725 trade name]* Darunavir 800 mg Tablets
- 2. Statement of active substance**
Each tablet contains 800 mg darunavir.
- 3. List of excipients**
- 4. Pharmaceutical form and contents**
Tablets
30 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 light and moisture. Avoid excursions above 30°C.
- 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**
MSN Laboratories Private Limited
“MSN House”, Plot No. C-24
Industrial Estate, Sanath Nagar
Hyderabad, Telangana, 500 018, India
- 12. WHO Reference Number (Prequalification Programme)**
HA725
- 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**

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