

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA742 trade name]* Atazanavir (as sulfate)/ritonavir 300 mg/100 mg film-coated tablets

Atazanavir (as sulfate)/ritonavir

2. Statement of active substance

Each film-coated tablet contains 341.7 mg atazanavir sulfate equivalent to 300 mg atazanavir and 100 mg ritonavir

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

30 film-coated tablets

90 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. Protect from 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

No special requirements

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

11. Name and address of the supplier

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai – 400063
India

12. WHO Reference Number (Prequalification Programme)

HA742

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