

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle label

1. Name of the medicinal product

[HA720 trade name]¹ Atazanavir (as sulphate) /ritonavir 300 mg/100 mg tablets
Atazanavir (as sulphate) /ritonavir

2. Statement of active substance

Each tablet contains 341.708 mg atazanavir sulfate equivalent to 300 mg atazanavir and 100 mg ritonavir.

3. List of excipients

Each tablet contains about 167.3 mg of lactose monohydrate.

4. Pharmaceutical form and contents

30 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. Store in the original container. 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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway,

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Atazanavir (as sulfate)/ ritonavir
300mg/100mg film-coated tablets (Lupin
Limited), HA720

WHOPAR Part 5

September 2022

Santacruz (East), Mumbai 400055,
India

12. WHO Reference Number (Prequalification Programme)

HA720

13. Manufacturer's batch number

<Batch> { number }

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use