LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA772 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

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. Store in the original container.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

Laurus Labs Limited 2nd Floor, Serene Chambers, Road No.-7

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

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Atazanavir (as sulfate)/ritonavir 300 mg/100 mg tablets (Laurus Labs Ltd.), HA772

Banjara Hills, Hyderabad Telangana – 500034 India.

12. WHO Reference Number (Prequalification Programme)

HA772

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