

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle and carton label

1. Name of the medicinal product

[HA389 trade name]¹ Efavirenz 200 mg Tablets

Efavirenz

2. Statement of active substance

Each film-coated tablet contains 200 mg Efavirenz

3. List of excipients

Contains lactose

See patient information leaflet for further information

4. Pharmaceutical form and contents

90 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 reach and sight 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. Protect from light.

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

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

Strides Pharma Science Limited
Strides House, Opp. IIMB,
Bilekahalli, Bannerghatta Road
Bangalore
Karnataka - 560076
India

12. WHO Reference Number (Prequalification Programme)

HA389

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