

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton and bottle label/HDPE

1. Name of the medicinal product

[HA306 trade name]*

Efavirenz 600 mg tablets

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

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 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

11. Name and address of the supplier

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway

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

Goregaon (East)
Mumbai 400 063
India

12. WHO Reference Number (Prequalification Programme)

HA306

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blisters outer carton

1. Name of the medicinal product

[HA306 trade name][†]

Efavirenz 600 mg tablets

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

3 x 10 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

11. Name and address of the supplier

Sun Pharmaceutical Industries Limited
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Goregaon (East)
Mumbai 400 063
India

12. WHO Reference Number (Prequalification Programme)

HA306

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister (Alu-Alu and Alu-PVdC/PE/PVC)

1. Name of the medicinal product

[HA306 trade name]

Efavirenz 600 mg tablets

2. Name of the supplier

Sun Pharmaceutical Industries Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other