

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton and HDPE bottle

1. Name of the medicinal product

[HA306 trade name]* Efavirenz 600 mg film-coated tablets

Efavirenz

2. Statement of active substance

Each film coated tablet contains 600 mg efavirenz

3. List of excipients

Each tablet contains about 226 mg of lactose as lactose monohydrate

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

5. Method and route of administration

Oral use.

Do not chew.

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

* 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 400 063
India

12. WHO Reference Number (Prequalification Programme)

HA306

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton (blister)

1. Name of the medicinal product

[HA306 trade name][†] Efavirenz 600 mg film-coated tablets

Efavirenz

2. Statement of active substance

Each film coated tablet contains 600 mg efavirenz

3. List of excipients

Each tablet contains about 226 mg of lactose as lactose monohydrate

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

3 x 10 tablets

5. Method and route of administration

Oral use.

Do not chew.

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

[†] 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 400 063
India

12. WHO Reference Number (Prequalification Programme)

HA306

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

1. Name of the medicinal product

[HA306 trade name] Efavirenz 600 mg film-coated tablets

Efavirenz

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