

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle label

1. Name of the medicinal product

[HA633 trade name]* Efavirenz 600 mg tablets

Efavirenz

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz.

3. List of excipients

Contains lactose.

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 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

Micro Labs Limited
31, Race Course Road
Bangalore – 560001
Karnataka
India

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

12. WHO Reference Number (Prequalification Programme)

HA633

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

Carton label

1. Name of the medicinal product

[HA633 trade name][†] Efavirenz 600 mg tablets

Efavirenz

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz.

3. List of excipients

Contains lactose.

4. Pharmaceutical form and contents

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.

Keep the blisters in the provided carton.

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

Micro Labs Limited
31, Race Course Road
Bangalore – 560001
Karnataka

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

India

12. WHO Reference Number (Prequalification Programme)

HA633

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

1. Name of the medicinal product

[HA633 trade name] Efavirenz 600 mg tablets
Efavirenz

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other