

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton (white or blue HDPE bottles)

1. Name of the medicinal product

[HA403 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

See patient information leaflet for further information

4. Pharmaceutical form and contents

30 tablets

28 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. Protect from moisture.

Store in the provided 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.

†Formerly known as Matrix Laboratories Limited

11. Name and address of the supplier

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096,
Telangana,
India

[Email: ProductSafety@viatris.com](mailto:ProductSafety@viatris.com)

12. WHO Reference Number (Prequalification Programme)

HA403

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

Bottle label (white or blue HDPE bottles)

1. Name of the medicinal product

[HA403 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

See patient information leaflet for further information

4. Pharmaceutical form and contents

30 tablets

28 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. Protect from moisture.

Store in the provided 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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096,
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12. WHO Reference Number (Prequalification Programme)

HA403

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

Blister carton

1. Name of the medicinal product

[HA403 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

See patient information leaflet for further information

4. Pharmaceutical form and contents

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. Protect from moisture.

Store in the provided 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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills

Hyderabad - 500096,
Telangana,
India

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12. WHO Reference Number (Prequalification Programme)

HA403

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

PVdC-coated PVC film with backing of aluminium foil coated with heat seal lacquer

1. Name of the medicinal product

[HA403 trade name]*

Efavirenz 600 mg tablets

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other