LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label
Blister carton label

1. NAME OF THE MEDICINAL PRODUCT

[HA426 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg lamivudine, 200 mg nevirapine and 300 mg zidovudine.

3. LIST OF EXCIPIENTS

Contains lactose
See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

60 film-coated tablets
6 x 10 film-coated tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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

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

[1] Formerly Matrix Laboratories Ltd

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original package. Protect from light.

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 - 500034,
Telangana,
India
Tel No: +91 40 39258109
Email: imtiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA426

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

[HA426 trade name]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg lamivudine, 200 mg nevirapine and 300 mg zidovudine.

3. LIST OF EXCIPIENTS

Contains lactose
See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

60 film-coated tablets.

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 package. Protect from light.

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 - 500034,
Telangana,
India
Tel No: +91 40 39258109
Email: imtiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA426

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

[HA426 trade name]

2. NAME OF THE SUPPLIER

Mylan Laboratories Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}