

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. NAME OF THE MEDICINAL PRODUCT

[HA433 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each dispersible tablet contains 30 mg lamivudine, 50 mg nevirapine and 60 mg zidovudine.

3. LIST OF EXCIPIENTS

Contains aspartame and lactose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

60 dispersible 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 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

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

¹ Formerly Matrix Laboratories Ltd

Do not store above 30 °C. Store in the original package, protected from moisture. Keep the bottle tightly closed.

Once dispersed in water, the mixture should be used within 10 minutes.

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

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA433

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE