

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle and carton label (HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

[HA524 trade name] *

2. STATEMENT OF ACTIVE SUBSTANCE

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

3. LIST OF EXCIPIENTS

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 patient information leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Strides Pharma Science Limited
Strides House, Bilekahalli,
Bannerghatta Road,
Bangalore – 560 076
India.

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA524

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE