Lamivudine/Nevirapine/Zidovudine 30mg/50mg/60mg dispersible tablets, (Strides Pharma Science Limited) HA557

WHOPAR part 5

February 2020

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box/HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

Lamivudine/Nevirapine/Zidovudine dispersible Tablets 30/50/60 mg *

2. STATEMENT OF ACTIVE SUBSTANCE

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

3. LIST OF EXCIPIENTS

Contains lactose monohydrate

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

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

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C, Protect from light and moisture.

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, 560076 India.

Tel: +91-80-67840738/290 Email: sadiq.basha@strides.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA557

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE