LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA656 trade name]* Lamivudine/zidovudine 150 mg/300 mg tablet Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains lamivudine 150 mg and zidovudine 300 mg

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

60 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 light. Store in the original package.

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.

Page 2 of 5

11. Name and address of the supplier

Anhui Biochem Bio-Pharmaceutical Co., Ltd

No. 30 Hongfeng Road, Hi-Tech Development Zone, Hefei City,

Anhui Province, 230088,

People's Republic of China

12. WHO Reference Number (Prequalification Programme)

HA656

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

HDPE bottle label

1. Name of the medicinal product

[HA656 trade name]† Lamivudine/zidovudine 150 mg/300 mg tablet Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains lamivudine 150 mg and zidovudine 300 mg

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

60 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 light. Store in the original package

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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