

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

[HA060 trade name] Blister pack – OUTER CARTON

1. Name of the medicinal product

[HA060 trade name]* 150 mg/300 mg film-coated tablets

Lamivudine, Zidovudine

2. Statement of active substance

Each film-coated tablet of [HA060 trade name] contains lamivudine 150 mg and zidovudine 300 mg

3. List of excipients

4. Pharmaceutical form and contents

10 film-coated tablets

14 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 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

Store below 30°C.

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.

11. Name and address of the supplier

Cipla Ltd
Cipla House, Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai 400013
India

12. WHO Reference Number (Prequalification Programme)

HA060

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

1. Name of the medicinal product

[HA060 trade name] film-coated tablets

Lamivudine 150 mg

Zidovudine 300 mg

2. Name of the supplier

Cipla Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

[HA060 trade name] HDPE Bottle – OUTER CARTON

1. Name of the medicinal product

[HA060 trade name][†] 150 mg/300 mg film-coated tablets

Lamivudine, Zidovudine

2. Statement of active substance

Each film-coated tablet of [HA060 trade name] contains lamivudine 150 mg and zidovudine 300 mg

3. List of excipients

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 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

Store below 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

Cipla Ltd
Cipla House, Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai 400013
India

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

12. WHO Reference Number (Prequalification Programme)

HA060

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

[HA060 trade name] HDPE Bottle

1. Name of the medicinal product and route of administration

[HA060 trade name] (lamivudine 150 mg + zidovudine 300 mg), film-coated tablets.

Oral use

2. Method of administration

Read the package leaflet before use

3. Expiry date

EXP {MM/YYYY}

4. Batch number

<Batch> <Lot> {number}

5. Contents by weight, by volume or by units

60 tablets