LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
HDPE bottle

1. Name of the medicinal product

[HA657 trade name]* Abacavir /Lamivudine 600 mg/ 300 mg tablets

Abacavir / Lamivudine

2. Statement of active substance

Each film coated tablet contains 600 mg of abacavir (as sulfate) and 300 mg of lamivudine

3. List of excipients

Contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 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

Detach Alert Card enclosed in the pack, it contains important safety information

WARNING! In case of any symptoms suggesting hypersensitivity reactions, contact your health care provider IMMEDIATELY.

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Do not remove the desiccant canister from the bottle.

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

Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018
Telangana, India.

12. WHO Reference Number (Prequalification Programme)

HA657

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

Blister carton

1. Name of the medicinal product

[HA657 trade name] Abacavir /Lamivudine 600 mg/ 300 mg tablets

Abacavir /Lamivudine

2. Statement of active substance

Each film coated tablet contains 600 mg of abacavir (as sulfate) and 300 mg of lamivudine

3. List of excipients

Contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

10 x 10 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

Detach Alert Card enclosed in the pack, it contains important safety information

WARNING! In case of any symptoms suggesting hypersensitivity reactions, contact your health care provider IMMEDIATELY.

8. Expiry date

EXP {MM/YYYY}

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

Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018
Telangana, India.

12. WHO Reference Number (Prequalification Programme)

HA657

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

[HA657 trade name] Abacavir / Lamivudine 600 mg/ 300 mg tablets

Abacavir / Lamivudine

2. Name of the supplier

Hetero Labs Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}