

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA740 trade name]¹ Abacavir (as sulfate)/lamivudine 600 mg/300 mg tablets
Abacavir (as sulfate)/lamivudine

2. Statement of active substance

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

Do not store above 30°C. Store in the original container.

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

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India.

12. WHO Reference Number (Prequalification Programme)

HA740

13. Manufacturer's batch number

<Batch> { 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

Carton (ALU/ALU-PVC Blister)

1. Name of the medicinal product

[HA740 trade name] Abacavir (as sulfate)/lamivudine 600 mg/300 mg tablets
Abacavir (as sulfate)/lamivudine

2. Statement of active substance

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

Film coated tablets
10 x 6's

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

Do not store above 30°C. Store in the original container.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India.

12. WHO Reference Number (Prequalification Programme)

HA740

13. Manufacturer's batch number

<Batch> { 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

BLISTER

1. Name of the medicinal product

[HA740 trade name] Abacavir (as sulfate)/lamivudine 600 mg/300 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other