

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle and carton label

1. Name of the medicinal product

[HA494 trade name]*

Abacavir (as sulfate) 300 mg tablets

2. Statement of active substance

Each film-coated tablet contains 351.3 mg abacavir sulfate equivalent to 300 mg abacavir.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

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

Strides Pharma Science Limited
Bilekahalli, Bannerghatta Road
Bangalore -560076, India
Tel : 91-80-67840738/739
Fax: 91-80-67840200

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

12. WHO Reference Number (Prequalification Programme)

HA494

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 IMMEDIATE PACKAGING

Bottle label

1. Name of the medicinal product

[HA494 trade name][†]

Abacavir (as sulfate) 300 mg tablets

2. Statement of active substance

Each film-coated tablet contains 351.3 mg abacavir sulfate equivalent to 300 mg abacavir.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

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

Strides Pharma Science Limited
Bilekahalli, Bannerghatta Road
Bangalore -560076, India
Tel : 91-80-67840738/739
Fax: 91-80-67840200

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

12. WHO Reference Number (Prequalification Programme)

HA494

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

Blister

1. Name of the medicinal product

[HA494 trade name]

Abacavir (as sulfate) 300 mg tablets

2. Name of the supplier

Strides Pharma Science Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other