

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA568 trade name]* Nevirapine 50 mg Tablets

2. Statement of active substance

Each tablet contains nevirapine 50 mg

3. List of excipients

Contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

30 tablets

60 tablets

90 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 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

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

Micro Labs Limited

31, Race Course Road

Bangalore - 560001

Karnataka

India

12. WHO Reference Number (Prequalification Programme)

HA568

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

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

[HA568 trade name] Nevirapine 50 mg Tablets

2. Statement of active substance

Each tablet contains nevirapine 50 mg

3. List of excipients

Contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

3 x 10 tablets

6 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 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

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

Micro Labs Limited

31, Race Course Road

Bangalore - 560001

Karnataka

India

12. WHO Reference Number (Prequalification Programme)

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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

PVC/PVDC-Al blisters

1. Name of the medicinal product

[HA568 trade name] Nevirapine 50 mg Tablets

2. Name of the supplier

Micro Labs Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other