

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

HDPE bottle

**1. Name of the medicinal product**

[HA569 trade name]\* Nevirapine 100 mg Tablets

**2. Statement of active substance**

Each tablet contains nevirapine 100 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

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

**12. WHO Reference Number (Prequalification Programme)**  
HA569

**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**

[HA569 trade name] Nevirapine 100 mg Tablets

**2. Statement of active substance**

Each tablet contains nevirapine 100 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)**

HA569

**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**

[HA569 trade name] Nevirapine 100 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**