

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA510 trade name] *

nevirapine 50 mg dispersible tablets

2. Statement of active substance

Each uncoated dispersible tablet contains 50 mg nevirapine (as anhydrate).

3. List of excipients

Contains aspartame and lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablet

60 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

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

11. Name and address of the supplier

Cipla Limited
Cipla House,
Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai -400013,
India

12. WHO Reference Number (Prequalification Programme)

HA510

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

Carton

16. Name of the medicinal product

[HA510 trade name]

nevirapine 50 mg dispersible tablets

17. Statement of active substance

Each uncoated dispersible tablet contains 50 mg nevirapine (as anhydrate).

18. List of excipients

Contains aspartame and lactose.

See the patient information leaflet for further information.

19. Pharmaceutical form and contents

Dispersible tablet

6 x 10 tablets

20. Method and route of administration

Oral use.

Read the patient information leaflet before use.

21. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach of children.

22. Other special warning(s), if necessary

23. Expiry date

EXP {MM/YYYY}

24. Special storage conditions

Do not store above 30°C.

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

26. Name and address of the supplier

Cipla Limited

Cipla House,

Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai -400013,
India

27. WHO Reference Number (Prequalification Programme)

HA510

28. Manufacturer's batch number

<Batch> <Lot> {number}

29. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

30. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

PVC/PE/PVDC-Al blister

1. Name of the medicinal product

[HA510 trade name]

nevirapine 50 mg dispersible tablets

2. Name of the supplier

Cipla Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other