LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

100 mL and 240 mL PET bottle carton

1. Name of the medicinal product

[HA200 trade name][*]

Nevirapine 50 mg/5 mL suspension

2. Statement of active substance

The suspension contains 50 mg/5 mL nevirapine (as hemihydrate).

3. List of excipients

Contains sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

100 mL oral suspension

240 mL oral suspension

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

Store below 30°C.

The oral suspension should be used within one month after first opening.

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 Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India
Tel: +91-22-24826000
Email: globalra@cipla.com

12. WHO Reference Number (Prequalification Programme)

HA200

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 OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

25-mL glass bottle

1. Name of the medicinal product

[HA200 trade name][†]

Nevirapine 50 mg/5 mL suspension

2. Statement of active substance

The suspension contains 50 mg/5 mL nevirapine (as hemihydrate).

3. List of excipients

Contains sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

25 mL oral suspension

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

Store below 30°C.

The oral suspension should be used within one month after first opening.

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.

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12. WHO Reference Number (Prequalification Programme)

HA200

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 OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

10 mL glass bottle

1. Name of the medicinal product

[HA200 trade name][‡]

Nevirapine 50 mg/5 mL suspension

2. Statement of active substance

The suspension contains 50 mg/5 mL nevirapine (as hemihydrate).

3. List of excipients

Contains sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

10 mL oral suspension

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

Store below 30°C.

The oral suspension should be used within one month after first opening.

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.

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Email: globalra@cipla.com

12. WHO Reference Number (Prequalification Programme)

HA200

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