

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle/HDPE

1. Name of the medicinal product

[HP035 trade name]* entecavir 0.5 mg tablets

Entecavir

2. Statement of active substance

Entecavir (monohydrate) 0.5 mg

3. List of excipients

See patient information leaflet

4. Pharmaceutical form and contents

Film-coated tablets

1 x 30

1x 100

5. Method and route of administration

Oral use.

Do not chew.

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

None

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

None

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

11. Name and address of the supplier

RV Lifesciences Limited
Plot No. H-19, MIDC, Waluj,
Aurangabad 431133,
Maharashtra State,
India

12. WHO Reference Number (Prequalification Programme)

HA035

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 pack/Aluminium-Aluminium

1. Name of the medicinal product

[HP035 trade name] entecavir 0.5 mg tablets

Entecavir

2. Name of the supplier

RV Lifesciences Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other