

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HP002 trade name]* Sofosbuvir 400mg film-coated tablets
Sofosbuvir

2. Statement of active substance

Each tablet contains 400 mg sofosbuvir

3. List of excipients

Contains FD&C yellow #6/sunset yellow FCF aluminium lake
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

14 tablets

28 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 this medicine out of the sight and 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

Hetero Labs Limited,
7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar, Hyderabad-500 018.
Telangana, India.
Tel: +91 40 23704923/ 24/25 /26 /27/28
+91 40 23707171 / 7272 / 7744

12. WHO Reference Number (Prequalification Programme)

HP002

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

Outer carton

1. Name of the medicinal product

[HP002 trade name][†] Sofosbuvir 400mg film-coated tablets
Sofosbuvir

2. Statement of active substance

Each tablet contains 400 mg sofosbuvir

3. List of excipients

Contains FD&C yellow #6/sunset yellow FCF aluminium lake
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets
10 x 10

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 this medicine out of the sight and 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

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12. WHO Reference Number (Prequalification Programme)

HP002

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
Alu-Alu blister cards

1. Name of the medicinal product

[HP002 trade name][‡] Sofosbuvir 400mg film-coated tablets
Sofosbuvir

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

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