

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HP009 trade name]* Sofosbuvir 400 mg tablets

Sofosbuvir

2. Statement of active substance

Each film-coated tablet contains 400 mg sofosbuvir.

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

28 tablets

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

8. Expiry date

EXP MM/YYYY

9. Special storage conditions

Do not store above 30°C, avoid excursions 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

Strides Pharma Science Limited
Strides House, Opp IIMB
Bilekahalli, Bannerghatta Road
Bangalore, Karnataka
560 076
India

12. WHO Reference Number (Prequalification Programme)

HP009

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

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HDPE bottle label

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