

## **LABELING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Label/ white or blue HDPE bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

Sofosbuvir Tablets, Film-coated 400 mg\*

**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**

28 film-coated 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 and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

---

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

<b>9. SPECIAL STORAGE CONDITIONS</b>
--------------------------------------

Do not store above 30°C. Store in the original container.

<b>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</b>
--

<b>11. NAME AND ADDRESS OF THE SUPPLIER</b>
---

Mylan Laboratories Limited  
Plot No. 564/A/22, Road No. 92, Jubilee Hills  
Hyderabad – 500096  
Telangana  
India

<b>12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)</b>
--

HP001

<b>13. MANUFACTURER'S BATCH NUMBER</b>
--

<Batch> {number}

<b>14. GENERAL CLASSIFICATION FOR SUPPLY</b>
--

Medicinal product subject to medical prescription.

<b>15. INSTRUCTIONS ON USE</b>
--------------------------------