

## **LABELLING**

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

**Carton and bottle label (HDPE bottle)**

**1. NAME OF THE MEDICINAL PRODUCT**

TENVIR-M\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each film-coated tablet contains 200mg emtricitabine and 300mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

**3. LIST OF EXCIPIENTS**

Contains lactose

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

30 film coated tablets

90 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**

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\* 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.

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C, protect from moisture.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS  
OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF  
APPROPRIATE**

**11. NAME AND ADDRESS OF THE SUPPLIER**

Sun Pharmaceutical Industries Limited  
Sun House, 201 B/1,  
Western Express Highway,  
Goregaon (East)  
Mumbai – 400063, India

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA551

**13. MANUFACTURER'S BATCH NUMBER**

<Batch><Lot> <BN> {number}

**14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**