

Emtricitabine/Tenofovir Disoproxil Fumarate 200/300 mg tablets (Strides Pharma Science Ltd), HA552	WHOPAR part 5	August 2020
--	---------------	-------------

## **LABELLING**

Emtricitabine/Tenofovir Disoproxil Fumarate 200/300 mg tablets (Strides Pharma Science Ltd), HA552	WHOPAR part 5	August 2020
--	---------------	-------------

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **Carton label**

#### **1. NAME OF THE MEDICINAL PRODUCT**

[HA552 trade name]\*

#### **2. STATEMENT OF ACTIVE SUBSTANCE**

Each film-coated tablet contains 200 mg 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.

#### **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**

---

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

Emtricitabine/Tenofovir Disoproxil Fumarate 200/300 mg tablets (Strides Pharma Science Ltd), HA552	WHOPAR part 5	August 2020
--	---------------	-------------

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C

**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**

Strides Pharma Science Limited  
Strides House, Bilekahalli  
Bannerghatta Road  
Bangalore – 560 076  
India  
Tel: +91-80-67840738/290  
Email: [Sadiq.basha@strides.com](mailto:Sadiq.basha@strides.com)

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

HA552

**13. MANUFACTURER'S BATCH NUMBER**

&lt;Batch&gt; &lt;Lot&gt; &lt;BN&gt; {number}

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

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

Emtricitabine/Tenofovir Disoproxil Fumarate 200/300 mg tablets (Strides Pharma Science Ltd), HA552	WHOPAR part 5	August 2020
--	---------------	-------------

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA552 trade name]

**2. NAME OF THE SUPPLIER**

Strides Pharma Science Ltd

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch No> or <Lot> or <BN> {number}