



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## **URGENT MEDICINE RECALL\***

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2020-RN-01478-1

DATE AGREED: 21/12/2020

**PRODUCT:** **TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tenofovir disoproxil maleate 300 mg and emtricitabine 200 mg film coated tablet bottle**

All batches within expiry

ARTG: 265834

**SPONSOR:** Alphapharm Pty Ltd

**PHONE:** 1800 274 276 - Alphapharm

**REASON:** Alphapharm has received reported complaints of broken and/or split tablets from certain listed batches of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets.  
In the event a broken/split tablet is consumed, this may result in an ineffective dose if the tablet is not taken in its entirety.

**PROPOSED CUSTOMER ACTIONS:** Wholesalers:  
Wholesalers are asked to inspect their holdings and quarantine all stock of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets.

Pharmacists:  
Please place all stock on immediate hold, and return to the primary wholesale supplier for a refund.  
If patients return impacted product, please provide a refund and dispense an alternative brand.

Consumers:  
Patients that have any units from un-expired batches should return it to their pharmacist for a refund.  
Patients that have been prescribed Tenofovir Disoproxil Emtricitabine Mylan 300/200 should consult their treating physician for individual advice.

A TGA web statement will be published regarding this matter

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 2446 pharmacies nationally

Product export status: Unknown

This issue was first identified by the Sponsor

\*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>