GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

ترخيص رقم 00047 – 59 - 32 - 101
رقم العضوية 68583

Title: Batch Recall

VIREAD ® (Tenofovir) 245 mg Film-Coated Tablets (EU/1/01/200/001-002)

March 11th, 2014

Dear Pharmacist,

We wish to advise you that the following batches of VIREAD ® (Tenofovir) 245 mg Film-Coated Tablets 30-count bottles EU/1/01/200/001-002, are being recalled with immediate effect.

Lot Number	Expiration Date
KFBSD	12 2017
KFBTD	12 2017

The recall is going to pharmacy level.

The reason for the recall is due to possible presence of silicone rubber in the above listed product and lots. A failure of equipment used in the manufacture of the active pharmaceutical ingredient formulated in these medicinal product batches may have resulted in damage to silicone gaskets and silicone fragments entering the product in these recalled lots.

The recalled products were distributed in Saudi Arabia beginning in 05 Nov 2013.

The recall is limited to the specific product(s) and lot(s) listed above. No other lots of VIREAD ® (Tenofovir) **or any other products are included in this recall.**

ص . ب 309 الرياض 11411 المملكة العربية السعودية ، هاتف 4642826 ، فاكس 4653185

P.O. Box 309 Riyadh 11411 Saudi Arabia Tel.: (01) 464 2826 Fax: (01) 465 3185

All wholesale and retail pharmacy customers of the lots listed above are being notified of this recall.

We appreciate your cooperation in promptly responding to this matter.

ACTION REQUIRED:

1. Check your inventory and immediately quarantine any Viread with the lot numbers referenced above. These lots were first sold by GSK in Nov 2013
2. Stop dispensing the recalled lots immediately and segregate from your inventory for return.

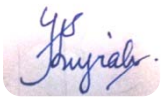
Call for reporting

GlaxoSmithKline will continue to monitor the safety of VIREAD ® (Tenofovir) and update SFDA of any serious adverse event for evaluation. You can assist us in monitoring the safety of VIREAD ® (Tenofovir) by reporting adverse reactions to fax: +966 12 6536660 or by email to GlaxoSmithKline safety email: faisal.m.shujrah@gsk.com or to the National Pharmacovigilance and Drug Safety Center at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa

If you have any question about the new information, please contact GSK medical information department at GlaxoSmithKline Saudi Arabia by phone: +966 12 6536666 or fax: +966 12 6536660.

The letter is sent in agreement with the Saudi Food and Drug Authority

Best regards;



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