IMPORTANT
DRUG
WARNING

December 23, 2020

COUNTERFEIT PRODUCT LABELED AS SYMTUZA®
(darunavir/cobicistat/emtricitabine/tenofovir alafenamide)
IN THE UNITED STATES

Dear Healthcare Professional,

Janssen Therapeutics, Division of Janssen Products, LP (Janssen) has become aware of at least 3 different instances in the United States in which a bottle that appeared to be labeled as SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) contained tablets of a different product. The different product tablets were not the yellow to yellowish-brown, capsule-shaped, film-coated tablets described further in the attachment.

Investigations to date have demonstrated that these counterfeit products were obtained through distributors that are not authorized distributors of record of JOM Pharmaceutical Services, Inc. (JOM), the Janssen affiliate distributing product to wholesalers. **We are confident that SYMTUZA® obtained through JOM's authorized distributors of record remains authentic.** A list of these authorized distributors of record is available at: https://www.jom.com/product.html?id=3026.

We are working with the US Food and Drug Administration (FDA) and law enforcement to aid in their evaluations, determine the source of the counterfeit product, and prevent its further distribution.

We are sending this communication to both pharmacists and SYMTUZA® prescribers in the United States, asking them to take the following actions to inform patients who have received SYMTUZA® of this Important Drug Warning. **Patients who may have counterfeit product in their possession should be supplied authentic SYMTUZA® as soon as possible to ensure adequate continuation of antiretroviral treatment.**

PHARMACIST ACTION:

If your pharmacy purchased SYMTUZA® from a source that is not a JOM authorized distributor of record, then Janssen advises you and your staff to do the following to ensure that patients do not have counterfeit SYMTUZA® in their possession and do not receive counterfeit SYMTUZA® in the future:

1. Contact your patients who may have received SYMTUZA® product obtained from a source that is not a JOM authorized distributor of record within the past 90 days and inform them of the issue.
2. Ask your patients if their tablets appear different from previous refills. If unclear, or they are a new patient, ask them to bring their tablets back to you for inspection. For new prescriptions or refills, open one SYMTUZA® bottle at the time of dispensation and inspect the tablets to ensure that they align to the image in the attachment. Dispense the medication in the original bottle with the original desiccant. When dispensing multiple bottles of SYMTUZA®, open only one bottle. Ensure that patients understand how to identify authentic SYMTUZA® tablets and instruct them to inspect the remainder of their supply at the time of use.
    - SYMTUZA® remains stable for 6 weeks at 25°C/60% relative humidity and 30°C/75% relative humidity after the seal has been broken when stored in final packaging equipped with 3 g desiccant.

3. If the tablets differ in appearance from the image below, or if the security seal was not intact, please contact the FDA's Office of Criminal Investigations (OCI) at 1-800-551-3989 (http://www.fda.gov/OCI) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736).

PRESCRIBER ACTION:

Janssen advises the following to ensure that your patients have not received counterfeit SYMTUZA®:

1. Contact your patients who are actively prescribed SYMTUZA® and inform them of the issue.
    a. Ask your patients if their tablets appear different from previous refills or ask them to bring their tablets back to you or their pharmacist for inspection if they are unsure.
    b. Ensure that the dispensed product in the patient's possession aligns to the image in the attachment.
2. If the tablets differ in appearance from the image attachment, or if the security seal was not intact, please contact Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736).

If you have any product in your possession that you suspect may be counterfeit, or if you suspect a patient may have received counterfeit drug, you should immediately contact the FDA's OCI at 1-800-551-3989 (http://www.fda.gov/OCI) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736).

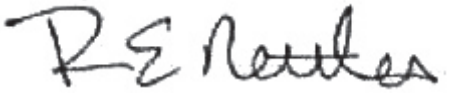
If you are aware of a patient experiencing any adverse effects that you think may be related to SYMTUZA® or to the use of a counterfeit drug, please immediately call FDA's MedWatch Program (1-800-FDA-1088) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736). Please refer to full Prescribing Information for SYMTUZA®, including Boxed Warning, available at: http://www.janssenlabels.com/package-insert/product- monograph/prescribing-information/SYMTUZA-pi.pdf.

Nothing is more important to Janssen than ensuring the health and safety of patients who rely on our medicines. Counterfeit drugs have serious implications for public health and safety, and we take the issue extremely seriously. Janssen Pharmaceutical Companies have implemented various approaches to combat counterfeiting that include working with relevant stakeholders to secure the distribution system and implementing special packaging and printing techniques that make counterfeits more difficult to make and easier to identify.

Thank you for your vigilance in monitoring the supply of SYMTUZA® and your support to ensure patients are made aware of the situation and the steps they can take to ensure they have authentic medicine.

If you have any other questions or require additional information, please contact the Janssen Medical Information Center:

Phone: 1-800-JANSSEN (1-800-526-7736)
E-mail: Janssenmedinfo@its.jnj.com
Website: www.JanssenMD.com



Rick Nettles, MD
Vice President Medical Affairs – Infectious Diseases and Vaccines
Janssen Scientific Affairs, LLC

Attachment:

SYMTUZA® Tablet Image

SYMTUZA® tablets are supplied as yellow to yellowish-brown, capsule-shaped, film-coated tablets debossed with “8121” on one side and “JG” on the other side.