Media Statement

December 24, 2020

Janssen Alerts Counterfeit SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide) is Being Distributed in the United States

The Janssen Pharmaceutical Companies of Johnson & Johnson have been made aware that counterfeit SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide) has been distributed to three pharmacies in the United States.

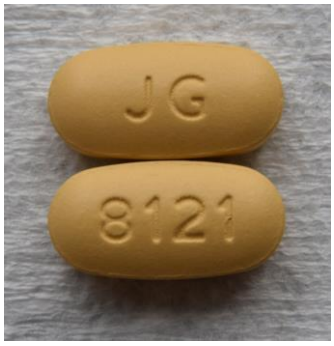
Janssen is working closely with the U.S. Food and Drug Administration (FDA) to prevent further distribution and to support the Agency's investigation into the reported instances. The pharmacies involved procured the counterfeit product from distributors that have not been authorized by Janssen. Janssen is confident that SYMTUZA® obtained through authorized distributors is authentic and safe for use.

Counterfeit medicines can place patient health at risk, and Janssen has implemented various approaches to combat counterfeiting. This includes working with stakeholders to secure the distribution system and implementing special packaging and printing techniques that make counterfeit product more difficult to produce and easier to identify. Patients and healthcare providers can be assured that Janssen is doing everything possible to address this issue and reduce the risk to patients as a result of this illegal act.

SYMTUZA® is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 88 pounds (40 kg) who have no prior antiretroviral treatment history or who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months, and have no known substitutions associated with resistance to darunavir or tenofovir.

"Nothing is more important to Janssen than ensuring the health and safety of the patients who rely on our medicines," said Rick Nettles MD, Vice President, U.S. Medical Affairs, Infectious Diseases & Vaccines, Janssen Therapeutics, Janssen Scientific Affairs, LLC. "We have begun informing prescribers and pharmacists about the situation and are providing guidance on how to identify authentic SYMTUZA® tablets. We are also enlisting the help of the strong HIV-patient advocacy community to ensure patients receive this information in a timely manner."

Janssen is aware of no reported adverse events related to the use of the counterfeit product at this time, but cautions that it is critically important that patients receive the medication they have been prescribed in order to adequately control their disease. FDA-approved 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, as shown below:



Tablets in a SYMTUZA® bottle that do not match this description should be reported immediately to the FDA's Office of Criminal Investigations (OCI) by calling 1-800-551-3989 (http://www.fda.gov/OCI) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736), or at https://AskJanssenMedicalInformation.com

If patients identify counterfeit product, they should contact their prescriber immediately to ensure they can access authentic SYMTUZA®. If a patient is experiencing any adverse effects that may be related to SYMTUZA® or to the use of counterfeit drug, they should immediately contact FDA's MedWatch Program (1-800-FDA-1088) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736), or at https://AskJanssenMedicalInformation.com

WHAT IS SYMTUZA®?
SYMTUZA® is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and in children who weigh at least 88 pounds (40 kg) who have not received anti-HIV-1 medicines in the past, or when their healthcare provider determines that they meet certain requirements.
HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if SYMTUZA® is safe and effective in children weighing less than 88 pounds (40 kg).

IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMTUZA®?
SYMTUZA® can cause serious side effects including:

- **Worsening of hepatitis B virus infection.** Your healthcare provider will test you for hepatitis B virus (HBV) before starting treatment with SYMTUZA®. If you have HBV infection and take SYMTUZA®, your HBV may get worse (flare-up) if you stop taking SYMTUZA®.
  - Do not stop taking SYMTUZA® without first talking to your healthcare provider.
  - Do not run out of SYMTUZA®. Refill your prescription or talk to your healthcare provider before your SYMTUZA® is all gone.
  - If you stop taking SYMTUZA®, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection or give you a medicine to treat your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking SYMTUZA®.
- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with SYMTUZA®. Liver problems can also happen during treatment with SYMTUZA® in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with SYMTUZA®.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
  - Skin or the white part of your eyes turn yellow
  - Dark "tea-colored" urine
  - Light-colored stools
  - Loss of appetite for several days or longer
  - Nausea
  - Vomiting
  - Stomach area pain

SYMTUZA® may cause severe or life-threatening skin reactions or rashes which may sometimes require treatment in a hospital. Call your healthcare provider right away if you develop a rash. **Stop taking SYMTUZA®** and call your healthcare provider right away if you develop any skin changes with symptoms including fever, mouth sores or ulcers, tiredness, red or inflamed eyes like "pink eye" (conjunctivitis), muscle or joint pain, blisters or skin lesions.

Who should not take SYMTUZA®?

- Do not take SYMTUZA® with any of the following medicines: alfuzosin, carbamazepine, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (such as: dihydroergotamine, ergotamine tartrate, methylergonovine), ivabradine, lomitapide, lovastatin or a product that contains lovastatin, lurasidone, midazolam (when taken by mouth), naloxegol, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John's wort (Hypericum perforatum) or a product that contains St. John's wort, sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin, or triazolam.
- Serious problems can happen if you take any of these medicines with SYMTUZA®.

Before taking SYMTUZA®, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems (including hepatitis B or hepatitis C), have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition.
- are pregnant (if you become pregnant while taking SYMTUZA®), or plan to become pregnant. It is unknown if SYMTUZA® will harm your unborn baby.
- SYMTUZA® should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take SYMTUZA®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with SYMTUZA®. Keep a list of your medicines to show your healthcare provider and pharmacist.

Do not start taking a new medicine without telling your healthcare provider.

HOW SHOULD I TAKE SYMTUZA®?

Take SYMTUZA® 1 time a day with food.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF SYMTUZA®?

SYMTUZA® may cause serious side effects including:

- See **"What is the most important information I should know about SYMTUZA®?"**
- **Immune system changes can happen in people who start HIV medications.**
- **New or worse kidney problems, including kidney failure.**
  - Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking SYMTUZA®.
- **Too much lactic acid in your blood (lactic acidosis).**
  - Too much lactic acid is a serious but rare medical emergency that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
    - weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including SYMTUZA® can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking SYMTUZA®.
- **Changes in body fat** can happen in people taking HIV-1 medications.
- **Increased bleeding** can occur in people with hemophilia who are taking SYMTUZA®.

The most common side effects of SYMTUZA® are: Diarrhea, rash, nausea, fatigue, headache, stomach problems, and gas. These are not all of the possible side effects of SYMTUZA®.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *http://www.fda.gov/medwatch* **or call 1-800-FDA-1088.** You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Please see full Product Information, including Boxed Warning for SYMTUZA®.
cp-62077v4

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS. Janssen Therapeutics is a Division of Janssen Products, LP. one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding SYMTUZA®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Products, LP, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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