

**SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide),
PREZCOBIX® (darunavir/cobicistat), PREZISTA® (darunavir), INTELENCE®
(etravirine), and EDURANT® (rilpivirine) -
Counterfeit Products**

SUMMARY

- In November 2020, Janssen was made aware that counterfeit SYMTUZA® was being distributed to pharmacies in the United States.¹
- Since then, additional reports of potential counterfeit Janssen HIV medications, including PREZCOBIX®, PREZISTA®, INTELENCE®, and EDURANT® have been received.
- On April 26, 2022, the Company announced that they have filed a lawsuit in the United States District Court for the Eastern District of New York seeking seizure of counterfeit product from unauthorized distributors of Janssen's medicines. Please click here for a link to the [Media Statement](#).²
- No adverse events or negative medical outcomes have been reported in relation to any instances of the potential counterfeit medication.
- Almost all instances involved procurement of product from distributors that are not authorized by Janssen.
- Janssen is confident in its supply chain controls and pharmacies should only obtain our medicines through authorized distributors.
 - Pharmacists can find a list of distributors authorized by Janssen at: <https://www.jom.com/authorizedDistributors.html>.
- Janssen continues to monitor for instances of counterfeit HIV medications and is working closely with the U.S. Food and Drug Administration (FDA) to support the Agency's investigation into all reported instances and to ensure appropriate legal action is taken against all those involved.
- As this is an active investigation, we are unable to provide further information at this time.

AUTHENTIC JANSSEN HIV TABLETS VS COUNTERFEIT TABLETS

A patient, healthcare provider, or pharmacist can identify authentic HIV medicines versus a counterfeit form by looking at the tablet. Janssen HIV tablet descriptions are provided below.³

SYMTUZA®

SYMTUZA® tablets are yellow to yellowish-brown, capsule-shaped, film-coated tablets debossed with "8121" on one side and "JG" on the other side.^{3, 4}



PREZCOBIX®

PREZCOBIX® tablets are pink, oval-shaped, film-coated tablets debossed with "TG" on one side and "800" on the other side.^{3, 5}



PREZISTA® 800 mg

PREZISTA® 800 mg tablets are dark red, oval-shaped, film-coated tablets debossed with "T" on one side and "800" on the other side.^{3, 6}



PREZISTA® 600 mg

PREZISTA® 600 mg tablets are orange, oval-shaped, film-coated tablets debossed with "TMC" on one side and "600MG" on the other side.^{3, 6}



PREZISTA® 150 mg

PREZISTA® 150 mg tablets are white, oval-shaped, film-coated tablets debossed with "150" on one side and "TMC" on the other side.^{3, 6}



PREZISTA® 75 mg

PREZISTA® 75 mg tablets are white, caplet-shaped, film-coated tablets debossed with "75" on one side and "TMC" on the other side.^{3, 6}



EDURANT®

EDURANT® tablets are white to off-white, film-coated, round, biconvex, 6.4 mm tablets debossed with "TMC" on one side and "25" on the other side.^{1, 7}



INTELENCE® 200 mg

INTELENCE® 200 mg tablets are white to off-white, biconvex, oblong tablets debossed with "T200" on one side.^{3, 8}



INTELENCE® 100 mg

INTELENCE® 100 mg tablets are white to off-white oval tablets debossed with "TMC125" on one side and "100" on the other side.^{1, 7}



INTELENCE® 25 mg

INTELENCE® 25 mg tablets are white to off-white, oval, scored tablets debossed with “TMC” on one side.^{1, 7}



WHAT TO DO IF COUNTERFEIT MEDICINE IS SUSPECTED

- If tablets in any bottle of Janssen medication do not match the description of the prescribed product, this should be reported immediately to 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 by emailing Janssenmedinfo@its.jnj.com.
- If patients identify counterfeit product, they should not take the suspect medication and should contact their prescriber immediately to ensure they can access authentic HIV medication to ensure adequate continuation of antiretroviral treatment.
- If a patient is experiencing any adverse effects related to Janssen medicines or to the use of counterfeit medicines, they should immediately call FDA’s MedWatch Program (1-800-FDA-1088) or Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736), or email Janssenmedinfo@its.jnj.com.

REFERENCES

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2. Janssen Pharmaceutical Companies of Johnson & Johnson. Janssen Takes Further Legal Action to Help End the Distribution of Counterfeit HIV Medicines in the United States. Available at: https://www.janssen.com/us/sites/www_janssen_com_usa/files/janssen_takes_further_legal_action_to_help_end_the_distribution_of_counterfeit_hiv_medicines_in_the_united_states.pdf.
3. Data on File. Guidelines for Product Appearance/Physical Description Inspection. TV-WI-15525; April 2021.
4. SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SYMTUZA-pi.pdf>.
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6. PREZISTA (darunavir) [Prescribing Information]. Titusville, NJ: Janssen Therapeutics, Division of Janssen Products, LP; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PREZISTA-pi.pdf>.
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8. INTELENCE (etravirine) [Prescribing Information]. Titusville, NJ: Janssen Therapeutics, Division of Janssen Products, L.P.; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INTELENCE-pi.pdf>.