

Yesintek[™] (ustekinumab-kfce) – New biosimilar approval

- On December 1, 2024, <u>Biocon announced</u> the <u>FDA approval</u> of <u>Yesintek (ustekinumab-kfce)</u>, biosimilar to Janssen's <u>Stelara[®] (ustekinumab)</u>.
 - <u>Wezlana[™] (ustekinumab-auub)</u> was the first FDA-approved biosimilar that is interchangeable to Stelara.
 - Additional biosimilars approved to Stelara include <u>Selarsdi[™]</u> (<u>ustekinumab-aekn</u>), <u>Pyzchiva[™]</u> (<u>ustekinumab-ttwe</u>), <u>Otulfi[™]</u> (<u>ustekinumab-aauz</u>), and <u>Imuldosa[™]</u> (<u>ustekinumab-slrf</u>).
- Yesintek, Imuldosa, Otulfi, Pyzchiva, Wezlana, Selarsdi and Stelara share the following indications:
 - Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy
 - Adults and pediatric patients 6 years and older with active psoriatic arthritis (PsA).
 - Adult patients with moderately to severely active Crohn's disease (CD), and
 - Adult patients with moderately to severely active ulcerative colitis (UC).
- The approval of Yesintek is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Stelara.
- Yesintek is biosimilar to Stelara and shares the same recommended dosing instructions and safety profile including warnings, precautions, and adverse reactions.
 - Refer to the Yesintek drug label for additional details.
- Biocon plans to launch Yesintek no later than February 22, 2025. Yesintek will be available as a single-dose vial containing 130 mg/26 mL (5 mg/mL) for IV infusion, and single-dose prefilled syringes containing 45 mg/0.5 mL and 90 mg/mL and a single-dose vial containing 45 mg/0.5 mL for SC injection.



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