Otulfi®
ustekinumab-aauz

FDA-approved interchangable biosimilar to Stelara® (ustekinumab) in the same indications[1]

OTULFI®: Committed to today & tomorrow

Forward-thinking partnership for the **ustekinumab** journey

FDA, US Food and Drug Administration.

INDICATIONS AND USAGE

OTULFI (ustekinumab-aauz) is an IL-12/23 antagonist indicated for treatment of:

- Adult patients with:
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Active psoriatic arthritis
  - Moderately to severely active Crohn's disease
  - Moderately to severely active ulcerative colitis
- Pediatric patients ≥6 years of age with:
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Active psoriatic arthritis

IMPORTANT SAFETY INFORMATION

OTULFI (ustekinumab-aauz) is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in OTULFI (ustekinumab-aauz).

INFECTIONS

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products.

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for OTULFI® (ustekinumab-aauz).

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FDA-APPROVED

OTULFI® (ustekinumab-aauz) met the FDA requirements for biosimilarity[2,3]

FDA-approved based on proven similarity to Stelara® (ustekinumab) in[1]:

- Pharmacokinetics/pharmacodynamics
- Efficacy, safety, and immunogenicity for ustekinumab-naive and switch patients

OTULFI has been studied in a **Phase 3 trial that included a switching arm** in patients with moderate to severe plaque psoriasis.[3]

Available in the same administration options as Stelara[4,5]

130-mg dose vial for IV infusion

Pre-filled syringes for SC injection

45-mg dose vial for SC injection

Images are for illustrative purposes only.

NDC Codes:	45-mg NDC Codes:	90-mg NDC Codes:	NDC Codes:
65219-828-05	65219-824-01	65219-826-26	65219-822-05
65219-0828-05	65219-0824-01	65219-0826-26	65219-0822-05

OTULFI's administration options enable your patients to keep using a familiar administration method

HCPCS Code: Q9999

FDA, US Food and Drug Administration; IV, intravenous; SC, subcutaneous.

IMPORTANT SAFETY INFORMATION (continued)

Serious infections requiring hospitalization, or otherwise clinically significant infections, reported in clinical trials included the following:

- Plaque psoriasis: diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, urinary tract infections
- Psoriatic arthritis: cholecystitis
- Crohn's disease: anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, *Listeria* meningitis
- Ulcerative colitis: gastroenteritis, ophthalmic herpes zoster, pneumonia, listeriosis

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ADMINISTRATION FEATURES

OTULFI® (ustekinumab-aauz) offers the same administration options as Stelara® (ustekinumab)[4,5]

130-mg dose vial for IV infusion

Features	OTULFI	Stelara
Each vial contains 130 mg/26 mL for easy weight-based dosing	✓	✓
Room temperature (up to 25°C) storage up to 7 hours after dilution	✓	✓
Shelf life of 24 months at 2°C to 8°C	✓	✓

Pre-filled syringes for SC injection

Features	OTULFI	Stelara
36-month product shelf life	✓	✓
Room temperature storage up to 30°C for up to 30 days	✓	✓
No natural rubber (latex)	✓	
29-gauge special thin-walled needle	✓	27-gauge
Safety needle guard	✓	✓

45-mg dose vial for SC injection

Features	OTULFI	Stelara
Each vial contains 45 mg/0.5 mL for easy weight-based dosing	✓	✓
Room temperature (up to 25°C) storage up to 24 hours after dilution	✓	✓
Shelf life of 24 months at 2°C to 8°C	✓	✓

IMPORTANT SAFETY INFORMATION (continued)

Avoid initiating treatment with OTULFI (ustekinumab-aauz) in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of OTULFI (ustekinumab-aauz) in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with OTULFI (ustekinumab-aauz).

Discontinue OTULFI (ustekinumab-aauz) for serious or clinically significant infections until the infection resolves or is adequately treated.

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ADMINISTRATION AND DOSING

OTULFI® (ustekinumab-aauz) has the same weight-based dosing as Stelara® (ustekinumab)[4,5]

Dosing for Crohn's disease or ulcerative colitis *(adult)*

Patient Weight	Induction Dose	Maintenance Dose
55 kg or less	260 mg administered intravenously using two 130-mg vials	90 mg administered subcutaneously every 8 weeks using the pre-filled syringe or two 45-mg vials
More than 55 kg and up to 85 kg	390 mg administered intravenously using three 130-mg vials	
More than 85 kg	520 mg administered intravenously using four 130-mg vials	

Dosing for plaque psoriasis *(adult and pediatric)*

Patient Weight	Dose
100 kg or less *(adults)*	45-mg initial dose, then 4 weeks later, then every 12 weeks
More than 100 kg *(adults)*	90-mg initial dose, then 4 weeks later, then every 12 weeks
Less than 60 kg *(aged 6-17 years)*	0.75-mg/kg initial dose, then 4 weeks later, then every 12 weeks
60 kg to 100 kg *(aged 6-17 years)*	45-mg initial dose, then 4 weeks later, then every 12 weeks
More than 100 kg *(aged 6-17 years)*	90-mg initial dose, then 4 weeks later, then every 12 weeks

Dosing for psoriatic arthritis *(adult and pediatric)*

Patient Weight	Dose
Any weight *(adults)*	45-mg initial dose, then 4 weeks later, then every 12 weeks
More than 100 kg with coexistent moderate to severe plaque psoriasis *(adults)*	90-mg initial dose, then 4 weeks later, then every 12 weeks
Less than 60 kg *(aged 6-17 years)*	0.75-mg/kg initial dose, then 4 weeks later, then every 12 weeks
60 kg or more *(aged 6-17 years)*	45-mg initial dose, then 4 weeks later, then every 12 weeks
More than 100 kg with coexistent moderate to severe plaque psoriasis *(aged 6-17 years)*	90-mg initial dose, then 4 weeks later, then every 12 weeks

IMPORTANT SAFETY INFORMATION (continued)

THEORETICAL RISK FOR VULNERABILITY TO PARTICULAR INFECTIONS

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), *Salmonella* (including nontyphi strains), and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients.

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KabiCare
Patient support from Fresenius Kabi

KabiCare® provides support to help patients access OTULFI

KabiCare offers a comprehensive range of patient support so that patients have the assistance they need to benefit most from their treatment.


Enrollment Support


Financial Support


Insurance Support


Clinical Support

With KabiCare, eligible patients prescribed OTULFI may be able to pay as little as $0/month in out-of-pocket costs*

To learn more about the KabiCare patient support program, visit **KabiCare.us**, or call **1.833.KABICARE (1-833-522-4227)**.

OTULFI offers additional educational tools and resources, including:

- Billing & coding guide
- Patient brochures
- Injection training videos

*Eligibility criteria apply. Patients are not eligible for commercial copay support if the prescription is eligible to be reimbursed, in whole or part, by any state or federal healthcare program.

IMPORTANT SAFETY INFORMATION (continued)

It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with ustekinumab products may be susceptible to these types of infections. Consider appropriate diagnostic testing (e.g., tissue culture, stool culture, as dictated by clinical circumstances).

PRE-TREATMENT EVALUATION OF TUBERCULOSIS (TB)

Evaluate patients for TB prior to initiating treatment with OTULFI (ustekinumab-aauz).

Avoid administering OTULFI (ustekinumab-aauz) to patients with active TB infection. Initiate treatment of latent TB before administering OTULFI (ustekinumab-aauz). Consider anti-TB therapy prior to initiation of OTULFI (ustekinumab-aauz) in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Closely monitor patients receiving OTULFI (ustekinumab-aauz) for signs and symptoms of active TB during and after treatment.

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FRESENIUS KABI BIOSIMILARS

At Fresenius Kabi, our global expertise in complex medicine, state-of-the-art supply chain, and manufacturing enables us to deliver high-quality biosimilars.

Industry-leading portfolio of 6 FDA-approved biosimilar products in Immunology and Oncology with a growing pipeline

State-of-the-art facilities certified by major international regulatory agencies, including the FDA and the European Medicines Agency

Awards: Best-in-class customer service that has been recognized by multiple group purchasing organization awards (Vizient, Premier, HealthTrust)

FDA, US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (continued)

MALIGNANCIES

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among subjects who received ustekinumab in clinical trials. In rodent models, inhibition of IL-12/IL-23p40 increased the risk of malignancy.

The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer (NMSC). Monitor all patients receiving OTULFI (ustekinumab-aauz) for the appearance of NMSC. Closely follow patients >60 years of age, those with a medical history of prolonged immunosuppressant therapy, and those with a history PUVA treatment.

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue OTULFI (ustekinumab-aauz).

POSTERIOR REVERSIBLE ENCEPHALOPATHY SYNDROME (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after initiating ustekinumab products. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with OTULFI (ustekinumab-aauz) for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue OTULFI (ustekinumab-aauz).

ONBOARDING

Starting patients on OTULFI® (ustekinumab-aauz) is simple

1 Initiate a prescription

- For ease of prescribing, ensure OTULFI is saved to a Favorite Rx list in the EHR system

2 Confirm payer coverage through benefits investigation

3 Review educational materials with patients

4 Patients receive their first dose

- Current ustekinumab patients do not need to repeat their loading dose. OTULFI can be initiated as their next scheduled dose

EHR, electronic health record.

IMPORTANT SAFETY INFORMATION (continued)

IMMUNIZATIONS

Prior to initiating therapy with OTULFI (ustekinumab-aauz), patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with OTULFI (ustekinumab-aauz) should not receive live vaccines. Avoid administering BCG vaccines during treatment with OTULFI (ustekinumab-aauz), or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving OTULFI (ustekinumab-aauz) because of the potential risk for shedding from the household contact and transmission to patient.

Non-live vaccinations received during a course of OTULFI (ustekinumab-aauz) may not elicit an immune response sufficient to prevent disease.

NONINFECTIOUS PNEUMONIA

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue OTULFI (ustekinumab-aauz) and institute appropriate treatment.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (≥3%) seen in patients treated with OTULFI (ustekinumab-aauz) are:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, fatigue
- Crohn's disease, induction: vomiting
- Crohn's disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, nausea

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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OTULFI® (ustekinumab-aauz): Committed to today & tomorrow

FDA-approved interchangeable biosimilar to Stelara® (ustekinumab) with no clinically meaningful differences in efficacy, safety, or immunogenicity[1]

- Efficacy and safety were maintained over 1 year, including for patients who switched from Stelara® (ustekinumab) to OTULFI (ustekinumab-aauz)[3]
- Similar immunogenicity profile over 1 year compared with Stelara[1]

Flexible, easy-to-use administration options[4,5]

- Same administration options and weight-based dosing schedule as Stelara
- Only 4 to 6 injections per year
- Pre-filled syringe is equipped with a finer-gauge needle and a needle guard that does not contain dry natural rubber latex

KabiCare **Comprehensive patient support, including educational, financial, and treatment resources**

FDA, US Food and Drug Administration.

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References: 1. Data on file. Fresenius Kabi USA, LLC. **2.** US Food and Drug Administration. Biosimilar product regulatory review and approval. Accessed April 7, 2025. https://www.fda.gov/files/drugs/published/Biosimilar-Product-Regulatory-Review-and-Approval.pdf **3.** Papp K, Balser S, Nopora K, et al. A randomised, double-blind trial to compare the efficacy, safety, and immunogenicityof the biosimilar ustekinumab in patients with moderate-to-severe plaque psoriasis. *Adv Ther.* 2025;42(5):2135-2149. **4.** OTULFI Prescribing Information. Fresenius Kabi USA, LLC; May 2025. **5.** Stelara Prescribing Information. Janssen Pharmaceuticals, Inc; 2019.

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