

## Discover the OTULFI® experience



### Important Safety Information for OTULFI® (ustekinumab-aauz)

#### What is OTULFI (ustekinumab-aauz)?

OTULFI is a prescription medicine use to treat:

- Moderate-to-severe psoriasis (PsO) in adults and children 6 years and older who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills)
- Active psoriatic arthritis (PsA) in adults and children 6 years and older
- Moderately to severely active Crohn's disease (CD) in adults 18 years and older
- Moderately to severely active ulcerative colitis (UC) in adults 18 years and older

It is not known if OTULFI is safe and effective in children less than 6 years of age.

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

Please see Important Safety Information throughout this brochure and click to see [full Prescribing Information](#) and the Medication Guide, for OTULFI® (ustekinumab-aauz).

**OTULFI® (ustekinumab-aauz) is designed to help reduce inflammation, leading to fewer symptoms and less frequent flare-ups, making it effective for autoimmune disorders¹.**

## **What is OTULFI®¹,²?**

**OTULFI® is an FDA-approved biosimilar medicine to Stelara®(ustekinumab) used to treat:**

PsO

**Plaque Psoriasis**

PsA

**Psoriatic Arthritis**

CD

**Crohn's Disease**

UC

**Ulcerative Colitis**



Typically, doctors will prescribe OTULFI® infusion after someone has not responded to a different medication.

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### **Important Safety Information (continued)**

OTULFI is a prescription medicine that affects your immune system and can increase your chance of having serious side effects including:

#### **Serious Infections**





OTULFI may lower your ability to fight infections and may increase your risk of infections. While taking OTULFI, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

Please see Important Safety Information throughout this brochure and click to see [full Prescribing Information](#) and the Medication Guide, for OTULFI® (ustekinumab-aauz).

## What does it mean if your prescription medicine is an FDA-approved biosimilar<sup>1</sup>?

An FDA-approved biosimilar means that there are no clinically meaningful differences in effectiveness, safety, or purity between the biosimilar, like OTULFI®, and the reference (original product), like Stelara® (ustekinumab). Biosimilars are safe and effective.

### OTULFI® and Stelara® are similar in the following ways<sup>3</sup>:

-  **Made from living cells**
-  **Given the same way**
-  **Provide the same treatment benefits**
-  **Have the same potential side effects**

However, biosimilars are different in an important aspect of care that impacts everyone – cost. Biosimilars, like OTULFI®, are less expensive than their reference (original products), like Stelara®, which helps make critical medicines accessible to more patients.



**Biosimilars potentially offer up to 40% price reductions compared to reference products<sup>4</sup>**

### Important Safety Information (continued)

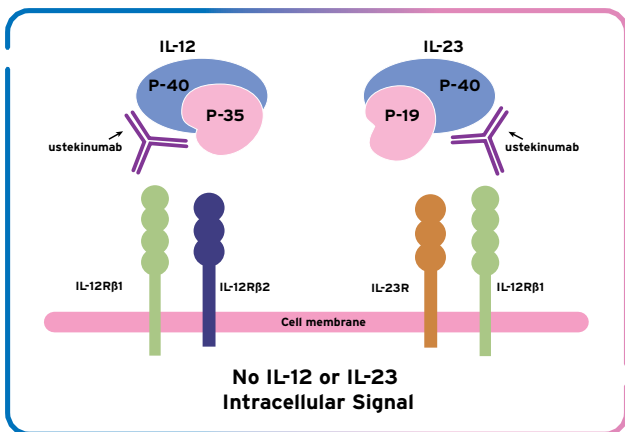
- Your doctor should check you for TB before starting OTULFI and monitor for signs and symptoms of TB when being treated with OTULFI
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with OTULFI

You should not begin treatment with OTULFI if you have any kind of infection unless your doctor says it is okay.

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## How does OTULFI® (ustekinumab-aauz) work¹?

In conditions treated by OTULFI®, your body may be producing two proteins interleukin 12 (IL-12) and interleukin (IL-23) at higher-than-normal levels, which may result in inflammation and pain. OTULFI® works by blocking the activity of IL-12 and IL-23 proteins, which has been shown to reduce inflammation, pain, swelling, and help with skin symptoms.



### Important Safety Information (continued)

#### Before starting OTULFI, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
  - fever, sweats, or chills
  - muscle aches
  - shortness of breath
  - cough
  - blood in phlegm
  - weight loss
  - feeling very tired
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
- have any open cuts or are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone with TB

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## How is OTULFI® administered?

OTULFI® can be given in the clinic by a healthcare professional or at home as a self-administered subcutaneous injection.

Your healthcare professional will determine the appropriate setting and administration method for your specific condition.

### Administered by your healthcare professional:

#### Vial for IV Infusion



**For patients with Crohn's disease and ulcerative colitis only**, an intravenous (IV) infusion may be given by your healthcare provider for your first dose. The medicine is administered using a needle placed in a vein in your arm. The infusion process will take place in your physician's office or an infusion center and will take about one hour. Follow-up doses will be given through a prefilled syringe.

### Administered by your healthcare professional or self-administered by you:

#### Vial for Subcutaneous Injection



**For patients with plaque psoriasis and psoriatic arthritis only**, your medicine will be prepared and given as an injection under your skin by your healthcare provider at your physician's office or by you at home.

### Important Safety Information (continued)

**After starting OTULFI, call your doctor right away** if you have any symptoms of an infection (see above). These may include signs of infections such as chest infections, skin infections, or shingles that could have serious complications. OTULFI can make it more likely for you to get infections or make an infection that you have worse.

People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for some serious infections that can spread throughout the body and cause death. People who take OTULFI may also be more likely to get these infections.

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## Self-administered by you:



### Single-use Prefilled Syringes (45 mg and 90 mg)

You will receive your medicine by injection under the skin using the prefilled syringe, which is a syringe that comes with medicine inside. The syringes come in 45 mg and 90 mg doses, depending upon the condition being treated.

It is important to read the **Instructions for Use** that come with your OTULFI® (ustekinumab-aauz) prescription about how to prepare and inject a dose of OTULFI® and how to properly throw away (dispose of) used needles and syringes. The syringe, needle, and vial must never be re-used. Throw away any unused portion of OTULFI®.

### Scan for instructional video on how to inject OTULFI® using a prefilled syringe



45 mg  
Prefilled Syringe



90 mg  
Prefilled Syringe

## Important Safety Information (continued)

### Cancers

OTULFI may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer before starting treatment with OTULFI.

Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving OTULFI. Tell your doctor if you have any new skin growths.

### Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. If PRES

Please see Important Safety Information throughout this brochure and click to see [full Prescribing Information](#) and the Medication Guide, for OTULFI® (ustekinumab-aauz).

## Helpful storage considerations<sup>1</sup>

- ▶ OTULFI® must be refrigerated between 2°C to 8°C (36°F to 46°F) in the original carton
- ▶ Do not freeze
- ▶ Store OTULFI® vials upright
- ▶ A single prefilled syringe or vial may be stored at room temperature at or below 30°C (86°F) for a single maximum period of up to 30 days
- ▶ Once a syringe or vial has been stored at room temperature, do not return to the refrigerator
- ▶ Protect the vials and syringes from light by storage in the original pack

## What should I do if I miss a dose<sup>1</sup>?

Take the missed dose as soon as you remember, then resume your usual dosing routine. Do not take two doses to make up for a missed one. If you're unsure when to take your next dose, talk with your healthcare provider for guidance.

**Talk to your healthcare provider if you or your caregiver have any questions about OTULFI®.**

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### Important Safety Information (continued)

is found early and treated, most people recover. The cause of PRES is not known. Tell your doctor right away if you have any new or worsening medical problems including headache, seizures, confusion, and vision problems.

#### **Serious Allergic Reactions**

Serious allergic reactions can occur during treatment with OTULFI. Stop using OTULFI and get medical help right away if you have any symptoms of a serious allergic reaction such as swelling of your face, eyelids, tongue, or throat; feeling faint; chest tightness; or skin rash.

Please see Important Safety Information throughout this brochure and click to see [full Prescribing Information](#) and the Medication Guide, for OTULFI® (ustekinumab-aauz).

## Fresenius Kabi provides you access to KabiCare™

KabiCare™ offers wide-ranging resources to supplement your experience with OTULFI® (ustekinumab-aauz). Your healthcare provider can enroll you in KabiCare™ at no cost.

### Support Offerings



#### Access to treatment

Benefit specialists provide assistance with navigating insurance to obtain coverage and reviewing patient benefits<sup>†</sup>



#### Clinical educators

Clinical educators are available to answer medical-related questions and provide injection training support for you and your caregivers<sup>†</sup>



#### Educational resources

Educational tools provide information on disease, medication, lifestyle modifications, and health and wellness

To learn more about the KabiCare™ patient support program, please scan the QR code or visit [www.kabicare.us](http://www.kabicare.us).



### Important Safety Information (continued)

#### Lung Inflammation

There have been some cases of lung inflammation in people who receive OTULFI. These cases may be serious and may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with OTULFI.

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## Financial support

KabiCare™ provides additional support programs to eligible patients.

### What type of insurance do you have?

#### Commercial or private insurance\*

If you have commercial or private insurance, you may be eligible for the copay assistance program that lowers out-of-pocket costs to as little as \$0/month for OTULFI®, with an annual maximum.

#### Government insurance (Medicare/Medicaid)†

If you have government insurance, but your plan does not cover OTULFI®, you may be eligible for assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs that may be able to help you afford OTULFI® copay costs.

#### Uninsured/Under-insured‡

If you do not have insurance and/or cannot afford OTULFI®, you may be eligible for additional assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs.

#### Pay as little as \$0 copay for each dose of OTULFI®

Ask your healthcare provider to help you enroll if you qualify for copay assistance.

If you receive prescription reimbursement through your local, state, or federal government, visit [Kabicare.us](https://www.kabicare.us) or call **1.833.KABICARE** (1-833-522-4227).

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

† Clinical support provided by KabiCare™ is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

‡ Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs.



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### Important Safety Information (continued)

#### **Before receiving OTULFI, tell your doctor about all of your medical conditions, including if you:**

- have any of the conditions or symptoms listed above for serious infections, cancers, or PRES
- ever had an allergic reaction to OTULFI or any of its ingredients (ask your doctor if you are not sure)
- have recently received or are scheduled to receive a vaccine
  - People who take OTULFI should not receive live vaccines
  - Tell your doctor if anyone in your house needs a live vaccine
  - The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems
  - You should not receive the BCG vaccine during the one year before receiving OTULFI or one year after you stop receiving OTULFI
- have any new or changing lesions within psoriasis areas or on normal skin
- receive or have received phototherapy for your psoriasis
- are receiving or have received allergy shots, especially for serious allergic reactions
- are pregnant or plan to become pregnant
  - It is not known if OTULFI can harm your unborn baby
  - You and your doctor should decide together if you will receive treatment with OTULFI
- received OTULFI while you were pregnant; it is important that you tell your baby's healthcare provider before your baby receives any vaccinations
- are breastfeeding or plan to breastfeed; OTULFI can pass into your breast milk
- talk to your doctor about the best way to feed your baby if you receive OTULFI

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take and keep a list of them to show your doctor and pharmacist when you get a new medicine.

#### **When prescribed OTULFI:**

- Use OTULFI exactly as your doctor tells you to
- OTULFI is intended for use under the guidance and supervision of your doctor.
  - In children 6 years and older, it is recommended that OTULFI be administered by a healthcare provider
  - If your doctor decides that you or a caregiver may give your injections of OTULFI at home, you should receive training on the right way to prepare and inject OTULFI

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### Important Safety Information (continued)

- Your doctor will determine the right dose of OTULFI for you, the amount for each injection, and how often you should receive it
- Do not try to inject OTULFI yourself until you or your caregiver have been shown how to inject OTULFI by your doctor or nurse

### Common side effects of OTULFI include:

- |                                |                                 |
|--------------------------------|---------------------------------|
| • nasal congestion             | • vomiting                      |
| • sore throat                  | • redness at the injection site |
| • runny nose                   | • vaginal yeast infections      |
| • upper respiratory infections | • urinary tract infections      |
| • fever                        | • sinus infection               |
| • headache                     | • bronchitis                    |
| • tiredness                    | • diarrhea                      |
| • itching                      | • stomach pain                  |
| • nausea                       | • joint pain                    |

These are not all of the possible side effects with OTULFI. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Fresenius Kabi at 1-800-551-7176.

**References:** **1.** OTULFI® (ustekinumab-aauz). Prescribing information. Fresenius Kabi, LLC; 2024. **2.** Stelara® (ustekinumab). Prescribing information. Janssen Biotech, Inc; 2024. **3.** Declerck P, Danesi R, Petersel D, Jacobs I. The Language of Biosimilars: Clarification, Definitions, and Regulatory Aspects. *Drugs*. 2017 Apr;77(6):671-677. doi: [10.1007/s40265-017-0717-1](https://doi.org/10.1007/s40265-017-0717-1). **4.** The U.S. Generic & Biosimilar Medicines Savings Report. September 2024. <https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf>. Accessed February 17, 2025.



# Additional patient support and resources

*We are committed to being your partner by providing support and resources for your journey with OTULFI® (ustekinumab-aauz)*



## To learn more

Scan the QR code for product information and dosing instructions



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