

Learn more about your treatment journey with IDACIO[®]



Important Safety Information About IDACIO[®]

WARNING: SERIOUS INFECTIONS and MALIGNANCY

See full prescribing information for complete boxed warning.

SERIOUS INFECTIONS (5.1, 6.1):

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
- Discontinue IDACIO[®] if a patient develops a serious infection or sepsis during treatment.
- Perform test for latent TB; if positive, start treatment for TB prior to starting IDACIO[®]
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

MALIGNANCY (5.2):

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products.
- Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with Inflammatory Bowel Disease treated with TNF blockers including adalimumab products.

What is the most important information I should know about IDACIO[®] (adalimumab-aacf)?

You should discuss the potential benefits and risks of IDACIO[®] with your healthcare provider.

IDACIO[®] is a TNF blocker medicine that affects your immune system. IDACIO[®] can lower the ability of your immune system to fight infections.

- **Serious infections have happened in people taking IDACIO[®]. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections.**

Please see Important Safety Information throughout this brochure and accompanying Full Prescribing Information, including **Boxed WARNING**, and Medication Guide for IDACIO[®] (adalimumab-aacf).

IDACIO[®] (adalimumab-aacf) is used to treat autoimmune diseases^{1,2}

Immune systems of people with certain conditions produce too much tumor necrosis factor (TNF), causing inflammation.

This inflammation can result in irritation, swelling, pain, and other discomfort inside and outside of the body.

For over a decade, physicians have prescribed adalimumab to manage the signs and symptoms of these conditions:

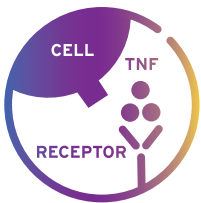
- Rheumatoid Arthritis
- Ulcerative Colitis in adults
- Psoriatic Arthritis
- Plaque Psoriasis
- Ankylosing Spondylitis
- Crohn's Disease
- Juvenile Idiopathic Arthritis



Scan this QR code to learn more about your specific condition.



How IDACIO[®] works in your body¹



Adalimumab products bind to TNF and block its interaction with specific receptors on different cells. Since these receptors receive signals from the immune system, medicines like IDACIO[®] can reduce or eliminate problematic inflammation.





IDACIO[®] (adalimumab-aacf) is an FDA-approved biosimilar for HUMIRA[®] (adalimumab)^{1*}

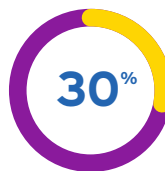
A biosimilar is a medicine that's highly similar to the original product.

Compared to the original product, a biosimilar has no clinically meaningful differences in safety, purity, or effectiveness.³

Biosimilars put critical medicine within reach of more patients compared to the more expensive reference biologic.

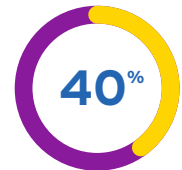
Both types of medicine:

- Are made from living cells
- Have the same level of purity
- Are as effective as one another
- Work the same way in your body



Biosimilars potentially offer up to 30% price reductions compared with reference products⁴

Biologics like HUMIRA[®] make up approximately 40% of the total prescription drug spending in the U.S.⁵



*Humira[®] is a registered trademark of AbbVie, Inc.

Important Safety Information (continued)

- Your healthcare provider should test you for TB before starting IDACIO[®].
- Your healthcare provider should check you closely for signs and symptoms of TB during treatment with IDACIO[®].
- You should not start taking IDACIO[®] if you have any kind of infection unless your healthcare provider says it is okay.
- **Cancer.** For children and adults taking TNF blockers, including IDACIO[®], the chance of getting lymphoma or other cancers may increase.
 - There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death.
 - If using TNF blockers including IDACIO[®], your chance of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your healthcare provider if you have a bump or open sore that doesn't heal.

What should I tell my healthcare provider BEFORE starting IDACIO[®]?

Tell your healthcare provider about all of your health conditions, including if you:

- Think you have an infection or have symptoms of an infection such as
 - Fever, sweats, or chills
 - Muscle aches
 - Cough
 - Shortness of breath
 - Blood in phlegm
 - Weight loss
- Are being treated for infection
- Get a lot of infections or infections that keep coming back
- Have diabetes
- Have TB or have been in close contact with someone with TB
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use IDACIO[®]. Ask your healthcare provider if you are unsure if you have lived in these areas
- Have or have had hepatitis B
- Have or had heart failure
- Have or had cancer
- Have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

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IDACIO[®] (adalimumab-aacf) is easy to use¹

You've been prescribed IDACIO[®], which is available as a prefilled autoinjector pen as well as a prefilled syringe with a dosage of 40 milligrams to be injected. No matter the device, preparing and injecting IDACIO[®] is easy.

Administering IDACIO[®] is simple

Follow the instructions you receive from your healthcare provider. We also have Instructions For Use (IFU) videos and printed instructions at www.idacio.com.



Prepare

- Wash your hands and examine the device for damage or expiration



Inject

- Choose the injection site (stomach or front of thighs) and make sure the area is clean



Dispose and document

- Properly dispose of the device and supplies in a sharps container, document your injection site, and date of therapy

Talk to your healthcare provider if you or your caregiver have any questions about IDACIO[®].

Storage and handling¹

Keep IDACIO[®] in the original carton to protect from light and store it in a refrigerator set between 36 and 46 degrees Fahrenheit or 2 and 8 degrees Celsius.

- Do not use IDACIO[®] if frozen, even if it has been thawed.
- Refrigerated IDACIO[®] may be used until the expiration date printed on the IDACIO[®] carton, dose tray, or pen.
- Do not use IDACIO[®] if the liquid is cloudy, discolored, or has flakes or particles in it.
- IDACIO[®] can be stored at room temperature for up to 28 days.
- Record the date you first remove IDACIO[®] from the refrigerator in the spaces provided on the carton.



Idacio[®]
adalimumab-aacf

IDACIO[®] comes in two unique devices¹

Be sure to watch the appropriate application video and read the instructions for use that come in each package.[†]



[†] This is not a substitute for reading the Medication Guide accompanying your IDACIO[®] prefilled syringe or prefilled autoinjector pen.

Important Safety Information (continued)

- Have recently received or are scheduled to receive a vaccine. You may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting IDACIO[®].
- Are scheduled for major surgery
- Are allergic to IDACIO[®] or to any of its ingredients.
- Are pregnant or plan to become pregnant, breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you should take IDACIO[®] while you are pregnant or breastfeeding.
- Have a baby and you were using IDACIO[®] during your pregnancy. Tell your baby's healthcare provider before your baby receives any vaccines.

Tell your healthcare provider about the medications you take. You should not take IDACIO[®] with ORENCIA[®] (abatacept), KINERET[®] (anakinra), REMICADE[®] (infliximab), ENBREL[®] (etanercept), CIMZIA[®] (certolizumab pegol), or SIMPONI[®] (golimumab). Tell your healthcare provider if you have ever used RITUXAN[®] (rituximab), IMURAN[®] (azathioprine), or PURINETHOL[®] (mercaptopurine, 6-MP).

What should I watch for AFTER starting IDACIO[®]?

After starting IDACIO[®], call your healthcare provider right away if you have an infection, or any sign of an infection. IDACIO[®] can make you more likely to get infections or make any infection that you may have worse. IDACIO[®] can cause serious side effects, including:

- **Serious infections.** Your healthcare provider will examine you for TB and perform a test to see if you have TB. If your healthcare provider feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with IDACIO[®] and during treatment with IDACIO[®]. Even if your TB test is negative your healthcare provider should carefully monitor you for TB infections while you are taking IDACIO[®]. People who had a negative TB skin test before receiving adalimumab products have developed active TB. Tell your healthcare provider if you have any of the following symptoms while taking or after taking IDACIO[®]:
 - Cough that does not go away
 - Weight loss
 - Low-grade fever
 - Loss of body fat and muscle (wasting)

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Patient support resources for IDACIO[®] (adalimumab-aacf)

Fresenius Kabi is committed to providing you comprehensive support throughout your treatment journey.



Access to treatment

- Assistance with navigating insurance to obtain coverage and reviewing patient benefits
- Financial assistance programs available, including copay assistance with out-of-pocket costs as little as \$0/month for eligible patients with commercial or private insurance[‡]



Nurse Educators

- Nurse educators are available to answer medical-related questions and provide injection training support for you and your caregivers



Educational resources

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

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

Important Safety Information (continued)

- **Hepatitis B infection in carriers of the virus.** If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use IDACIO[®]. Your healthcare provider should do blood tests before you start treatment, while you are using IDACIO[®], and for several months after you stop treatment with IDACIO[®]. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B infection:
 - Muscle aches
 - Feel very tired
 - Dark urine
 - Skin or eyes look yellow
 - Little or no appetite
 - Vomiting
 - Clay-colored bowel movements
 - Fever
 - Chills
 - Stomach discomfort
 - Skin rash
- **Allergic reactions.** Allergic reactions can happen in people who use IDACIO[®]. Call your healthcare provider or get medical help right away if you have any of these symptoms of a serious allergic reaction:
 - Hives
 - Trouble breathing
 - Swelling of your face, eyes, lips or mouth
- **Nervous system problems.** Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **New heart failure or worsening of heart failure you already have.** Call your healthcare provider right away if you get new worsening symptoms of heart failure while taking IDACIO[®], including:
 - Shortness of breath
 - Sudden weight gain
 - Swelling of your ankles or feet



Copay assistance[§] and 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 IDACIO®, with an annual maximum.

Government insurance (Medicare/Medicaid)

If you have government insurance, but your plan does not cover IDACIO®, 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 IDACIO® copay costs.^{||}

Uninsured/Underinsured

If you do not have insurance and/or cannot afford IDACIO® 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 IDACIO®[§]

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 whole or in part, by any state or federal healthcare program.

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

Important Safety Information (continued)

- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that gets worse in the sun. Symptoms may improve when you stop IDACIO®.
- **Liver problems.** Liver problems can happen in people who use TNF-blocker medicines. These problems can lead to liver failure and death. Call your healthcare provider right away if you have any of these symptoms:
 - Feel very tired
 - Poor appetite or vomiting
 - Skin or eyes look yellow
 - Pain on the right side of your stomach (abdomen)
- **Psoriasis.** Some people using adalimumab products had new psoriasis or worsening of psoriasis they already had. Tell your healthcare provider if you develop red scaly patches or raised bumps that are filled with pus. Your healthcare provider may decide to stop your treatment with IDACIO®.

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Idacio[®]
adalimumab-aacf

Additional patient support and resources

We are committed to being your partner in providing support and resources for your journey with IDACIO[®].



Visit IDACIO.com to learn more

For product information, dosing instructions, and specific disease education, scan the QR code or visit the IDACIO[®] website.

www.idacio.com



Important Safety Information (continued)

Call your healthcare provider or get medical care right away if you develop any of the above symptoms. Your treatment with IDACIO[®] may be stopped.

Common side effects of IDACIO[®] include:

- Injection site reactions: redness, rash, swelling, itching, or bruising. These symptoms usually will go away within a few days. Call your healthcare provider right away if you have pain, redness or swelling around the injection site that does not go away within a few days or gets worse.
 - Upper respiratory infections (including sinus infections)
 - Headaches
 - Rash

These are not all the possible side effects with IDACIO[®]. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

What is IDACIO[®]?

IDACIO[®] is a medicine called a Tumor Necrosis Factor (TNF) blocker. IDACIO[®] is used:

- **To reduce the signs and symptoms of:**
 - **Moderate to severe rheumatoid arthritis (RA) in adults.** IDACIO[®] can be used alone, with methotrexate, or with certain other medicines. IDACIO[®] may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years of age and older.** IDACIO[®] can be used alone or with methotrexate.
 - **Psoriatic arthritis (PsA) in adults.** IDACIO[®] can be used alone or with certain other medicines. IDACIO[®] may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **Ankylosing spondylitis (AS) in adults.**
- **To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **To treat moderate to severe ulcerative colitis (UC) in adults.** It is not known if IDACIO[®] is effective in people who stopped responding to or could not tolerate anti-TNF medicines.
- **To treat moderate to severe chronic plaque psoriasis (Ps) in adults** who are ready for systemic therapy or phototherapy, and are under the care of a healthcare provider who will decide if other systemic therapies are less appropriate.

This is the most important information to know about IDACIO[®]. For more information, talk to your healthcare provider.

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References: 1 IDACIO[®] (adalimumab-aacf) injection prescribing information. Lake Zurich, IL: Fresenius Kabi USA, LLC.; 2022. 2. HUMIRA[®] (adalimumab) injection prescribing information., North Chicago, IL: Abbvie, Inc.; 2021. 3. Declerck P, et al. *The language of biosimilars: Clarification, definitions, and regulatory aspects.* *Drugs.* 2017;77(6):671-677. 4. Kabir ER, Moreino SS, Siam MKS. *The breakthrough of biosimilars: A twist in the narrative of biological therapy.* *Biomolecules.* 2019;9(9):410. <https://pubmed.ncbi.nlm.nih.gov/31450637> 5. Inserro A, Enzi, Hassan. Introduce bipartisan bill to improve biosimilar education. *American Journal of Managed Care (AJMC).* Published May 27, 2019. Accessed February 17, 2023. <https://www.centerforbiosimilars.com/view/enzi-hassan-introduce-bipartisan-bill-to-improve-biosimilar-education>



**FRESENIUS
KABI**

caring for life