

# Inflammatory Bowel Disease<sup>1,2</sup>

Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), are chronic inflammatory conditions that affect the digestive tract. The exact cause of IBD is not fully understood, but it is believed to be a complex interplay between genetic, environmental, and immunologic factors.

The severity of IBD can vary greatly, from being a mild inconvenience to a debilitating condition that can lead to other complications.

## Signs and symptoms of Inflammatory Bowel Disease, Ulcerative Colitis, or Crohn's Disease<sup>1,3</sup>

The symptoms for IBD, CD, and UC are similar and can include diarrhea (often with blood or mucus), abdominal pain and cramping, rectal pain and bleeding, urgency to have a bowel movement, fatigue, loss of appetite, or unintended weight loss.



If you are experiencing symptoms of IBD, it is important to speak with your doctor to determine the best course of treatment.

## Causes of Inflammatory Bowel Disease<sup>1,3</sup>

IBD is understood to be an autoimmune disorder where the body's immune system attacks its own tissues. In IBD, it targets the digestive tract, causing chronic inflammation. Risk factors include family history, smoking, diet, and environmental conditions that can be modified to help reduce the risk of developing IBD.

Certain types of bacteria, such as *E. coli* and *Salmonella*, have been linked to the development of IBD.

## Managing Inflammatory Bowel Disease, Ulcerative Colitis, or Crohn's Disease<sup>4</sup>

There are several ways to improve your quality of life and manage your symptoms.

Here are some things you can do that may help:

**Diet.** Avoid triggers such as dairy, gluten, and spicy and fatty foods to help reduce inflammation. Choose a diet rich in fruit, vegetables, lean proteins and healthy fats.

**Manage stress.** Stress can worsen symptoms of IBD, so it is important to find ways to manage stress, such as exercise, meditation, yoga, or therapy.

**Quit smoking.** Smoking can worsen symptoms of Crohn's disease and increase the risk of complications, so quitting smoking is recommended.

**Take medication.** Along with other strategies for managing IBD, medications can ease symptoms and reduce inflammation. Ask your doctor if medication is right for you.



**IDACIO<sup>®</sup> offers two ways to treat IBD symptoms<sup>5</sup>:**



The IDACIO<sup>®</sup> prefilled autoinjector pen



The IDACIO<sup>®</sup> prefilled syringe

For more information visit:  
[www.idacio.com](http://www.idacio.com)

## **IDACIO<sup>®</sup> (adalimumab-aacf) is a safe and effective treatment for IBD<sup>5</sup>**

Your doctor has prescribed IDACIO<sup>®</sup>, an FDA-approved biosimilar for Humira<sup>®</sup> (adalimumab), to reduce your signs and symptoms of IBD, ulcerative colitis, or Crohn's disease.

With IBD, your body produces too much tumor necrosis factor (TNF), which causes inflammation. IDACIO<sup>®</sup> may help reduce inflammation by blocking the activity of TNF.

IDACIO<sup>®</sup> can make treatment more accessible and affordable for patients suffering from IBD.

### **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<sup>®</sup> 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<sup>®</sup>.
- 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.

Please see Important Safety Information (Continued) on the next page as well as click to see accompanying [Full Prescribing Information](#), including **Boxed WARNING**, Medication Guide, and Instructions for Use for IDACIO<sup>®</sup> (adalimumab-aacf).

**References:** 1. Centers for Disease Control and Prevention. (2022, April 13). What is inflammatory bowel disease (IBD)? Centers for Disease Control and Prevention. Retrieved April 3, 2023, from <https://www.cdc.gov/ibd/what-is-IBD.htm> 2. Inflammatory bowel disease - StatPearls - NCBI bookshelf. (n.d.). Retrieved April 4, 2023, from <https://www.ncbi.nlm.nih.gov/books/NBK470312/> 3. Mayo Foundation for Medical Education and Research. (2022, September 3). Inflammatory bowel disease (IBD). Mayo Clinic. Retrieved April 3, 2023, from <https://www.mayoclinic.org/diseases-conditions/inflammatory-bowel-disease/symptoms-causes/syc-20353315> 4. Mayo Foundation for Medical Education and Research. (2022, November 2). Irritable bowel syndrome. Mayo Clinic. Retrieved April 3, 2023, from <https://www.mayoclinic.org/diseases-conditions/irritable-bowel-syndrome/diagnosis-treatment/drc-20360064> 5. IDACIO<sup>®</sup> (adalimumab-aacf) injection prescribing information. Lake Zurich, IL: Fresenius Kabi USA, LLC.; 2022.

## Important Safety Information (Continued)



### Important Safety Information About IDACIO®

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.**

- 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 if 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
  - 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
- 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.
- 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)

• **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

• **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®.

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.

Click for Full Prescribing Information, including Boxed WARNING and the Medication Guide, for IDACIO® (adalimumab-aacf).

