

**Dear Patient,**

Your healthcare provider has prescribed IDACIO<sup>®</sup> (adalimumab-aacf) for you.

We are committed to providing you with essential information that may be helpful as you begin treatment with IDACIO<sup>®</sup>. The materials in this kit are designed to complement the instructions you received from your healthcare provider. It's important to follow their instructions to get the most out of your treatment. Please see accompanying Full Prescribing Information, including **Boxed WARNING**, and Medication Guide in the enclosed IDACIO<sup>®</sup> Patient Brochure.

We understand that starting a new medication can be overwhelming, but you can rest assured that we are here to support you throughout your treatment journey.

We aim to make your experience with IDACIO<sup>®</sup> as positive as possible.

Sincerely,

**Your Idacio Support Team**

## 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 health care provider.

Please see the Full Prescribing Information, including **Boxed WARNING** and the Medication Guide, for IDACIO®.