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Adalimumab-aacf made by Fresenius Kabi

1. **What is adalimumab-aacf?**
   Adalimumab-aacf is the unbranded name for Idacio® (adalimumab-aacf). Both unbranded adalimumab-aacf and Idacio (adalimumab-aacf) are made by Fresenius Kabi. Although adalimumab-aacf comes as an unbranded product, it is the same as to Idacio (adalimumab-aacf) and shares the same biosimilar license application (BLA).[1-2]

   Adalimumab-aacf or Idacio (adalimumab-aacf) is a tumor necrosis factor (TNF) blocker and a biosimilar to Humira®. As a monoclonal antibody, it binds TNFα and blocks its general cytokine effects that is responsible for mediating the inflammatory process involved with TNF-mediated cellular functions associated with a range of autoimmune disorders.[1-2]

   As a biosimilar to Humira, adalimumab-aacf is considered highly similar to and has no clinically meaningful differences than its reference product Humira (original biologic).[1-2] This means that you can expect the biosimilar to provide similar safety and efficacy as the reference product. Every biosimilar is approved by the FDA and has no clinically meaningful differences in terms of treatment risks and benefits as its reference product.

2. **Is adalimumab-aacf an interchangeable biosimilar for Humira?**
   Although adalimumab-aacf is a biosimilar for Humira, it is not interchangeable.

   This just means that if you are switching a patient from Humira to adalimumab-aacf, the pharmacy cannot automatically substitute adalimumab-aacf without your approval, and the pharmacist needs a new prescription for adalimumab-aacf.

   While adalimumab-aacf is not interchangeable, both biosimilars and interchangeable biosimilars for Humira are considered as safe and effective as Humira and can be prescribed in place of Humira with equal confidence. A Phase 3 study in adult patients with moderate to severe plaque psoriasis demonstrated that patients who switched from Humira to adalimumab-aacf showed no clinically meaningful differences from Humira in efficacy or safety.[15]

3. **What product concentration and dosage forms are available for adalimumab-aacf?**
   Humira and biosimilars to Humira are available in two different concentrations[1-12] (commonly referred to as high concentration and low concentration products), which determines how much volume the patient will need to inject for their dose.

   For example, for a typical 40mg dose,

   - A **high** concentration Humira or adalimumab biosimilar product is 40mg/0.4ml. Therefore, the injection amount for a 40mg dose is 0.4ml.
   - A **low** concentration Humira or adalimumab biosimilar product is 40mg/0.8ml. Therefore, the injection amount for a 40mg dose is 0.8ml.

   Adalimumab-aacf comes as **low** concentration product of 40mg/0.8mL.

If the patient is being transitioned from high concentration Humira or other adalimumab biosimilar product to adalimumab-aacf, this just means that the patient will see slightly more liquid in their prefilled syringe or pen (e.g., 0.8ml instead of 0.4ml for a typical 40mg dose).

Whether receiving a high or low concentration product, it is important to reassure the patient that the actual medication, dose, and its effectiveness would remain the same.

4. **Is adalimumab-aacf preservative-free?**
   Yes. Adalimumab-aacf is citrate-free.[1]

   Citrate is commonly used as a preservative. The benefit of a citrate-free product is primarily related to reduced injection site pain. Citrate can cause stinging when injected, so removing this can make the injection more comfortable for patients and potentially improve therapy adherence.[13-14]

How to prescribe

1. **Will I need to write a new prescription for my patient to switch them to adalimumab-aacf?**
   Yes. Because adalimumab-aacf is not an interchangeable biosimilar, the pharmacy cannot automatically substitute this if a patient is receiving Humira or another biosimilar product. A new prescription specifically for adalimumab-aacf is needed prior to and no later than 1/1/2025.

2. **How do I write specifically for adalimumab-aacf?**
   Write for "**adalimumab-aacf",** making sure to add on the 4-letter suffix "aacf" to adalimumab. This will prevent callbacks or clarification requests as to the biosimilar you are requesting or prescribing.

   Writing only "adalimumab" or "adalimumab - ok to substitute" will **NOT** be sufficient. Adding the 4-letter suffix to adalimumab is necessary to specify the biosimilar product being requested for the patient. Because adalimumab-aacf is not an interchangeable biosimilar, the pharmacist is not able to automatically substitute adalimumab (Humira) with adalimumab-aacf, without you specifically writing for this biosimilar product.

3. **What is the dosing for adalimumab-aacf?**
   Dosing follows similar dosage and administration to that of Humira. Patient dosage may vary by the patient's medical condition, age or weight. However, the typical dose and frequency of administration is usually 40mg every other week.

   For certain conditions like plaque psoriasis, uveitis, Crohn's disease, ulcerative colitis, or hidradenitis suppurativa, initial loading doses of 80mg or 160mg doses may be prescribed.

   For additional prescribing information, please refer to the FDA approved product insert for adalimumab-aacf at biospecialized.com/wp-content/uploads/2023/11/BLA-761255-Adalimumab-aacf_PI-16Nov2023-1.pdf.

Patient assistance

1. **What is the KabiCare Program for adalimumab-aacf?**
   Please refer to the enclosed brochure for information on the KabiCare Program.

2. **How do I request adalimumab-aacf samples from the manufacturer?**
   Yes. Fresenius Kabi offers a sampling program for adalimumab-aacf and is available to all prescribers. The samples will come in a carton of two single-dose pens. The outer packaging for the samples will have Idacio branding, but because the products are the same, you can utilize these samples for patients prescribed adalimumab-aacf. The program is administered via a third-party vendor (Cardinal Health) who processes the provider's request for samples.

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To request samples, Connect with a Specialist | IDACIO® (adalimumab-aacf), (idaciohcp.com/contact-sales-specialist) and complete the contact information (e.g., Name, E-mail Address, ZIP code, NPI, Specialty, etc.). This will make sure that you are connected with the appropriate Fresenius Kabi Immunology Sales Specialist (ISS) to fulfil your request.

Samples are ordered electronically and will be shipped by the third-party vendor to your office location.

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