

## **ADALIMUMAB**

### **What is Adalimumab?**

Adalimumab (Humira®) is an antibody against a pro-inflammatory protein (cytokine) called tumor necrosis factor  $\alpha$  (anti-TNF). It is approved for the treatment of Crohn's disease and ulcerative colitis.

### **How is it administered?**

Adalimumab is a self-administered subcutaneous injection. It can be given either using an auto-injector pen or as a pre-filled syringe with a needle. Both are equally effective. The common sites of administration are your thighs or in your abdomen.

The first dose is given as 160mg (2 pens). Two weeks later, you will receive 80mg (1 pens) and beginning 2 weeks after this dose, you will take 40mg every 2 weeks. Approximately half of the patients will need to increase the dose to 40mg once a week. You will receive teaching on how to do the injections at your first appointment which will be with an IBD nurse.

### **When can I expect to respond to Adalimumab?**

Some patients may feel a benefit within the first week of initiating therapy. Typically, up to 6 weeks is required to see a benefit, though many notice an improvement in their symptoms with the first two injections of Adalimumab.

Approximately 7 out of 10 patients will respond to Adalimumab. The medication may stop working in up to 10% of patients every year. To ensure that it remains effective, it is important to be regular in your injection schedule without gaps in treatment. Sometimes your doctor will also start a second immunosuppressive medication along with Adalimumab to help it work better and remain effective longer.

Studies have shown that early effective therapy for Crohn's disease or ulcerative colitis is associated with long-term benefit including decreasing likelihood of needing surgery or hospitalization for these conditions.

### **What testing is needed on Adalimumab therapy?**

You will need blood testing to check for exposure to hepatitis B and tuberculosis infection prior to beginning treatment with Adalimumab. You may also need testing for tuberculosis exposure annually. Blood counts and liver tests are routinely drawn every 4 months while on Adalimumab. At times, your doctor may also check your Adalimumab level to ensure that you are receiving adequate dosing.

### **What are the potential side effects related to Adalimumab?**

Side effects with Adalimumab are uncommon. Patients may develop allergic reactions to Adalimumab as with any other medication. This is uncommon and can be treated with steroids and anti-histamines.

Fewer than 10% of patients may develop an injection site reaction which is pain, redness, and swelling at the site of the injection. This usually does not last longer than 2-3 days after each injection and sometimes be treated with anti-histamine medications.

As with other medications that act on the immune system, Adalimumab can increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people. Significant medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Adalimumab can also increase the risk of lymphoma, a form of cancer of the lymph node. The frequency of this in the general population is estimated to be around 2 out of 10,000 people. In those on Adalimumab, this risk may increase to 3-4 in 10,000. Rarely, Adalimumab may cause immune mediated reactions such as psoriasis or lupus. These occur in 1-3% of patients.

Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), untreated active malignancy, prior history of melanoma, or history of congestive heart failure should discuss the safety of Adalimumab with their gastroenterologists.

Please see the medication package insert for the full list of potential side effects.

### **Is Adalimumab safe during pregnancy and breast feeding?**

Maternal and paternal use of Adalimumab has not been associated with impairment of fertility, miscarriage, birth defects, preterm birth, still births, or other adverse pregnancy outcomes. You may get your last dose of Adalimumab early in the third trimester of your pregnancy. If you are on Adalimumab during pregnancy, it is recommended that your infant not receive live virus vaccines such as the rotavirus vaccine within the first 6 months. It is safe to breastfeed while on Adalimumab. This has not been shown to have any adverse impact on the baby. It is important to discuss with your provider about continuing Adalimumab before and during and after pregnancy, but most patients will continue the treatment during their pregnancy.

### **Health maintenance on Adalimumab therapy**

It is important to be up to date with your health maintenance while on Adalimumab therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines. You should not receive live virus vaccines while on Adalimumab therapy or within 3 months of stopping (or starting it).

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and dermatologic (skin check-ups) for both men and women. Make sure to speak to your primary care doctor about whether you are up-to-date on all your cancer screening and immunizations.

### **What if my out-of-pocket costs are high with this treatment?**

There are a number of foundations that provide assistance to cover cost for patients on Adalimumab therapy. The manufacturer of adalimumab has a patient assistance program for patients on Adalimumab, called Humira Complete. Please go to <https://www.humira.com/humira-complete> for more information on this program.