

HUMIRA (Adalimumab)

INFORMATION FOR PATIENTS CONSIDERING HUMIRA INJECTION TREATMENT

Humira is an FDA approved medication for the treatment of moderate to severely active Crohn's disease and other inflammatory conditions. This medication acts by bonding tumor necrosis factor alpha (TNF) in the body. TNF is a chemical produced as part of the immune response that accumulates inflammation. In Crohn's disease the levels of TNF are increased and contribute to continued/ongoing inflammation. Blocking the action of TNF with Humira is shown to reduce inflammation and improve symptoms of Crohn's disease.

This medication is administered by subcutaneous injection. This is delivered as a loading dose involving four injections followed by two injections two weeks later followed by one injection every other week. For your first injection we will train you to do the injection and observe you for the first thirty to sixty minutes following the injection to make sure there is no evidence of reaction to the medication. The duration of treatment with these injections will be defined by your doctor. **Humira is very expensive and you will need to check with your insurance for coverage and copays.** Like all medical interventions, there are side effects and risks associated with Humira and these include:

1. **TB** – Humira is associated with a reactivation of tuberculosis (TB) infection in individuals previously or newly exposed to TB. You will be required to have a skin test prior to starting treatment, and once a year while receiving treatment with Humira. Additionally, you may be asked to have a chest x-ray to look for evidence of old or active TB. Let your doctor know if you have had a prior exposure or become exposed to someone with active TB.
2. **Hepatitis B** – The use of Humira may increase the risk of a flare of hepatitis B (HBV) in patients who are chronic carriers. In rare cases this has been fatal. Patients will be screened for prior evidence of hepatitis B infection prior to initiating Humira therapy. If you are exposed to Hepatitis B during treatment you should make your doctor aware.
3. **Serious Infections** – Humira affects the immune system and has been associated with serious and unusual infections. The most common side effects reported in association with Humira is upper respiratory like illnesses occurring in approximately 7% of patients. Usually these symptoms are mild and transient. More serious centralized infections including bacterial, fungal and viral infections may occur. The rate of these infections is low. You will need to let your doctor know if you have a persistent fever, cough, or flu like symptoms before or during Humira treatment, as these could be a sign of a serious infection.
4. **Allergic Reaction** – Humira is associated with allergic type reactions. Immediate reactions with the injections can include swelling and irritation at the injection site, rarely tongue or throat swelling, in addition to hives and difficulty breathing. Rarely this severe type of allergic reaction can be associated with a drop in blood pressure, chest pain, or shortness of breath. If you develop any of these symptoms, please let your physician know. The development to an allergic type reaction may limit your ability to receive this medication in the future.
5. **Cancer** – Patients with Crohn's disease have a slight risk in developing blood cell cancers including leukemia and lymphoma. Anti TNF therapy including Humira is linked to a slight increase risk in developing leukemia and lymphoma and very rarely T-cell lymphoma. These cancers are serious and can be fatal. Let your physician know if you develop swelling of your lymph nodes so they can be investigated further.
6. **Other Side Affect Considerations** - Patients with heart failure may experience worsening of symptoms if given Humira. There are rare reports of Humira and other TNF drugs causing neurological disease, lowering of blood counts, liver injury and development of lupus like symptoms.
7. **All Risks and Side Affects of Humira May Not Be Known Nor Are All the Long Term Risks Known.**
8. **Alternative Therapy** – There are many alternative therapies available. If any questions remain about alternative therapies, please discuss these with your physician.

Patient Signature: _____ Witness Signature: _____

Patient Name: _____ Chart#: _____ DOB: _____ Date: _____