Humira (TNF-α antagonist) Treatment Consent And Patient Information

Humira is prescribed based on laboratory test results showing that you have increased amounts of protein tumour necrosis factor alpha (TNF-α) in your blood or increased immune activity in your uterus which have been associated with recurrent miscarriage or repeated IVF failure.

Immunotherapy with Humira is, however, still a controversial approach. In other words, there is currently insufficient evidence to demonstrate its effectiveness. Humira lowers TNF-α levels and is licensed for treating rheumatoid arthritis, Crohn's disease, ankylosing spondylitis and other autoimmune diseases. Humira is given as a subcutaneous injection under the skin on the stomach or thigh two weeks apart. When treating arthritis the injections may continue for years or indefinitely.

For reproductive problems the injections are prescribed up to a maximum of four injections. TNF-α antagonists are **not licensed for reproductive immune therapy** and are prescribed on a named patient basis (off-label).

Although the NHS guidelines suggest that patients might stop Humira for 5 months before pregnancy, the Rheumatology guidelines by the British Society of Rheumatology and the British Health Professionals in Rheumatology, as well as the Royal College of Obstetricians and Gynaecologists (RCOG) acknowledge the safety of Humira during pregnancy up to 28 weeks gestation and beyond.

Side Effects

1. Skin irritation at the injection site or a rash, minor infections, bronchitis, bladder infections, upper respiratory infections like colds or headaches.

2. Serious infections occur in 4 for every 1000 treated each year as compared to the placebo group of 2 for every 1000 treated per year. These infections include pneumonia, diverticulitis and kidney infection.

3. Tuberculosis can be reactivated when using Humira. The incidence of reactivation in women living in the US and Canada was 0.07 per 100 patients per year. This means that 7 in 10,000 patients taking Humira for one year had a reactivation of tuberculosis

(TB). For this reason women who take this medicine should have a negative TB test. Otherwise, you may need to start on TB treatment before starting Humira or avoid taking Humira. If you are a Hepatitis B carrier, Humira may, very rarely, cause a reactivation of Hepatitis B virus. Patients who are positive for HBsAg need to have liver function tests performed and monitored throughout therapy, or avoid taking Humira.

4. Other very rare side effects include: Possible increased incidence of Lymphoma in patients on long term therapy. Decreased white blood cells, red blood cells and platelets (pancytopenia) have been reported. Patients who have a neurological disease such as multiple sclerosis, myasthenia gravis or Guillain-Barre syndrome should not take Humira and lupus-like syndrome may occur with a positive anti-nuclear antibody test.

NB: Antoni & Braun (2002) have concluded that apart from the risk of reactivating TB, other severe infections were not significantly increased compared to placebo. The lymphoma rate is also in the expected range. The development of ANAs, Lupus like syndromes, infusion reactions, allergic reactions, neurological disorders have been described but they seem to be rare and easy to treat. Roux, *et al* (2007) have concluded that to date there is no evidence that TNF-α antagonists are associated with embryo toxicity, teratogenicity or increased pregnancy loss.

What Should You Avoid While Taking Humira?

You should avoid contact with people who have colds or flu or other contagious diseases. Avoid taking live or attenuated vaccines. You should check with your doctor before receiving any vaccinations. You should report any fever, weight loss, chronic cough, difficulties with breathing, fatigue, easy bruising, joint pain, numbness and tingling in the legs or nausea and vomiting to your doctor.

WARNING: ***Please tell one of the team if you have had previous or current cancer or another serious condition as Humira may be contraindicated for you.***

HFEA view:
https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/

References

- The British Society for Rheumatology (BSR) and British Health Professionals (BHPR) guidelines on prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. Rheumatology 2016; 55: 1693-1697.

- Biologics in pregnancy – for the obstetrician. The Obstetrician & Gynaecologist 2016:18 25-32.

- Side Effects of Anti-TNF Therapy: Current Knowledge. Antoni C & Braun J. Clinical Experimental Rheumatology 2002: 30 152-157.

- Pregnancy in Rheumatology Patients Exposed to Anti-Tumour Necrosis Factor (TNF)-α Therapy. Rheumatology 2007: 46(4) 695-698.

I have read and understand the information given and the unproven nature of this treatment and I understand and agree to the risks. I also agree to have a TB blood test prior to starting the Humira treatment and will confirm it is negative before commencing treatment.

Patient Name:	**Patient Signature:**	**Date:**
Clinic staff Name:	**Clinic staff signature:**	**Date:**