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INFORMATION ON ADALIMUMAB (HUMIRA)

What is Adalimumab (Humira)?

- This is an injectable medication which blocks the action of an inflammatory molecule known as tumor necrosis factor alpha (TNF alpha).
- Adalimumab binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptor. Other mechanisms are also responsible for the action of this medication.
- It is used "off label" for several hair loss conditions meaning that it is not formally FDA approved and Health Canada approved for this condition but has been shown in some studies to provide potential benefit.

What is the dose of Adalimumab?

- For most patients, the dose is 40 mg of the medicine by subcutaneous injection every second week. The dose may be reduced or the frequency reduced in the future depending on the response of the patient.
- For patients with dissecting cellulitis, Dr Donovan may recommend 160 mg first dose and then 80 mg dose 2 weeks later (day 15) and then 40 mg every week starting 15 days after that.
- The medication is stored in the refrigerator.
- The medication is injected in the front thigh or lower belly area

There are many prefilled syringes available including

- 80 mg, 40 mg, 20 mg, 10 mg prefilled glass syringes
- 80 mg and 40 mg "HUMIRA Pen"

Who should NOT use Adalimumab?

Adalimumab may or may not be appropriate for everyone. Dr. Donovan may not use for patients who:

- Patients sensitive to latex as some parts of the injection needle systems may have latex.
- Have an infection, are being treated for infection, or have symptoms of an infection
- Get recurrent infections
- Have diabetes
- Have tuberculosis or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting 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 HUMIRA. Ask your doctor if you are unsure if you have lived in these areas
- Have or have had hepatitis B
- Are scheduled for major surgery (the drug must be stopped)
- Have cancer now or have had cancer in the past
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome
- Have heart failure now or had heart failure in the past
- Have a family history of multiple sclerosis
- Have recently received or are scheduled to receive a vaccine. HUMIRA patients may receive vaccines, except for live vaccines. Live vaccines are not allowed with his medication. Children should be brought up to date on all vaccines before starting HUMIRA
- Are allergic to rubber, latex, or any HUMIRA ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Are using methotrexate (Dr Donovan may adjust dosing)

What are the possible side effects of Adalimumab?

The most common side effects are upper respiratory infection signs (runny nose), Headaches, and injections site reactions (local reactions where the medication is injected).

- **Infections including a risk for serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle. Dr Donovan will recommend you have a TB test before starting Adalimumab to see if you have ever been exposed. Live vaccines should not be used while receiving adalimumab.
- **TIPS TO AVOID INFECTION WHILE ON ADALIMUMAB:**
 - a) Avoid close contact with people you know have an infection.
 - b) Wash your hands often and carry around a small bottle of antibacterial hand gel.
 - c) Brush your teeth regularly.
 - d) Stop smoking - if you are a smoker.
 - e) Store food properly and prepare properly.
 - f) Keep you higher risk areas of the home clean and hygienic, especially the kitchen, bathrooms and toilets.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of your face, eyes, lips, or mouth.
- **Problems with the nervous system.** Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness. These sorts of problems are often referred to as 'demyelinating conditions' and can resemble multiple sclerosis.
- **Reduced blood counts (decreased blood cells that help fight infections or stop bleeding).** Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **Heart failure (new heart failure or worsening of existing problems).** Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Rarely adalimumab can raise liver enzymes. Serious issues can also occur but these are rare. Symptoms of serious issues include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis (new or worsening).** Symptoms include red scaly patches or raised bumps that are filled with pus.
- **Cancer.** A very small increased risk of lymphoma and other cancers (mainly skin cancer) may be possible with adalimumab. This is not common. Some studies have suggested the there is no increased risk. Many of the studies on cancer risk came initially from studying patients with rheumatoid arthritis. Studies of other patient groups (inflammatory bowel disease psoriasis) have not consistently shown an increased risk of cancer.

What tests will be needed before taking Adalimumab?

You will need a panel of tests before starting Adalimumab. These are the tests your doctor will order:

- 1) Basic blood counts : CBC + differential
- 2) Liver tests: LFTs (ALT, AST, ALP, bilirubin, albumin), HbSAg, HbSAb, HCV, HAV
- 3) Kidney tests: Creatinine, BUN, urinalysis
- 4) Pregnancy test if female: + BHCG
- 5) CK levels
- 6) ANA
- 7) ESR, CRP
- 8) HIV tests
- 9) Chest X ray
- 10) PPD or Tuberculosis screening (Quantiferon testing)

Vaccinations may be needed before starting adalimumab as well. This may include the shingles vaccines.

STARTING Adalimumab

- Once you start, a nurse will connect with you to train you how to use the syringe or pen.
- It is very important that each patient understand how to inject this medicine

What tests will be needed after starting the Adalimumab?

To ensure that Adalimumab is safe for you, you will have frequent blood tests in the first few months. It is very important that you do these tests. If your schedule is too busy to allow you to do these blood tests on a regular basis, Dr. Donovan will not prescribe Adalimumab.

Tests needed after starting the Adalimumab:

This testing is done after the second week and then monthly for the first few months and then every 3-6 months

1. CBC, AST, ALT, creatinine, urinalysis, ANA, CK, ESR, CRP is the basic set
2. A complete panel may be ordered every 3-6 months

What should prompt me to stop Adalimumab?

Adalimumab may need to be stopped for many reasons including the ones listed here, but others might be relevant as well. Be sure to advise Dr Donovan if any concerns arise and he will advise if the medication needs to be stopped:

1. In an infection develops
2. Heart issues develop
3. Nervous system changes,
4. Changes in blood counts
5. Allergic reactions
6. Cancer develops
7. A patient is going for surgery (stop 1 week before and resume 1 week after)

What should I be doing while on Adalimumab?

1. Get your blood tests according to Dr Donovan's recommendations
2. The annual influenza vaccine is recommended.
3. The pneumonia vaccine can also be given according to guidelines (every 5 years).
4. Wear sunscreen to protect against skin cancer.
5. Get annual skin checks.
6. Report any unusual symptoms to the doctor

REMEMBER: The decision to use Adalimumab for your alopecia requires careful consideration. Each patient must weigh the risks and benefits of the medication with the way their hair loss impacts their life. Many patients taking Adalimumab do very well and have minimal side effects. It is important to remember that some patients do not experience regrowth of hair, and other treatments need to be considered.

HELPFUL NUMBERS HUMIRA CANADA - 1866 848 6472

