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A. INFORMATION ON TOFACITINIB FOR ALOPECIA AREATA

What is tofacitinib?

Tofacitinib is an immunosuppressive drug (medication) which is sometimes used to treat alopecia areata. The drug inhibits a very specific signal inside immune system cells known as JAK 1 and JAK3. Therefore, you may commonly hear these medications referred to as “JAK inhibitors.” Studies have shown tofacitinib to be helpful for some patients with alopecia areata.

The drug is formally approved for patients with rheumatoid arthritis and its use in alopecia areata is said to be “off label” meaning that it can be prescribed to patients but only under the care and direction of a physician.

What tests are needed before starting?

A scalp examination and blood tests are required.

a) We require blood tests for:

- CBC, TSH, ferritin, ESR, CRP
- Electrolytes (sodium, potassium), Vitamin B12
- Creatinine
- Cholesterol
- Liver function tests (AST, ALT, bilirubin)
- Urinalysis
- Magnesium
- CK
- HIV, Hepatitis C and Hepatitis B
- TB skin testing
- HCG pregnancy test (women) 24 hours before starting

a) We require also

- Baseline ECG (electrocardiogram)
- Blood pressure

What is the dose of tofacitinib that is used?

The dose of tofacitinib is gradually increased. We start

- 5 mg daily for one month
- 5 mg twice daily for two months
- Higher doses are possible, but many patients do not require higher doses

What tests are needed after starting?

We require the following tests to be done one week after starting, two weeks after starting, four weeks after starting, 8 weeks after starting and 12 weeks after starting

- CBC, ferritin, creatinine, AST, ALT, ALP, bilirubin, urinalysis, cholesterol, CK
- Blood pressure test every month for three months (this can be done at family doctor)
- Repeat ECG at 3 months (this can be arranged through the family doctor)
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Do women of childbearing age need to use contraception?

Yes, women must not become pregnant while taking tofacitinib.

What patient groups does Dr. Donovan not prescribe tofacitinib?

- Patients under 18 or above 65 (exceptions exist)
- Patients who are currently pregnant or who may become pregnant
- Patients using other immunosuppressive drugs like methotrexate or prednisone
- Patients with baseline heart rate less than 60.
- Patients with heart problems
- Patients taking NSAIDS or steroids (these are medications)
- Patients with a history of diverticulitis (a bowel problem)
- Patients with Hepatitis B or Hepatitis C
- Patients with any infections
- Women who are pregnant, may become pregnant or who are breastfeeding (nursing)
- Patients with a low neutrophil or lymphocyte count to start.
- Patients taking fluconazole, ketoconazole, rifampin or vaccines
- Patients with diabetes
- Patients with stomach ulcers
- Patients who abuse alcohol

What side effects are possible with tofacitinib?

The most common side effects of tofacitinib are:

- Upper respiratory tract infection
- Runny nose
- Urinary tract infection
- Headaches
- High blood pressure
- Diarrhea
- Upset stomach
- Increased cholesterol
- Increased muscle enzymes (CK)

Uncommon side effects of tofacitinib include:

- Low blood counts
- Vomiting
- Dizziness
- Shingles/ herpes zoster (painful rash with blisters)
- Back pain
- Swelling of legs and hands
- Development of the 'flu'
- Congestive heart failure
- Possible increased risk of malignancy
- Serious infections (about 2 % of patients)
- Reactivation of TB (a TB skin test is needed before receiving)
- Possible increased risk of cancer
- Decrease in heart rate
- Bowel perforation

