

USTEKINUMAB

What is Ustekinumab?

Ustekinumab (Stelara®) is an antibody that blocks specific pro-inflammatory proteins (cytokine) called interleukin-12 and interleukin-23. It is approved for the treatment of Crohn's disease and ulcerative colitis.

How is it administered?

Ustekinumab is administered intravenously via infusion for the first dose. A typical infusion takes 30 minutes.

Subsequent doses are as a self-administered injection using a pre-filled syringe. It is given at a dose of 90mg every 8 weeks, beginning 8 weeks after the first intravenous infusion. Some patients may need to shorten the interval between injections.

When can I expect to respond to Ustekinumab?

Some patients may feel a benefit within 2-3 weeks of therapy. Typically, it takes up to 6-8 weeks to notice a significant benefit.

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

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

What are the potential side effects related to Ustekinumab?

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

Local injection site reactions (pain, redness, and swelling at the site of injection) are uncommon and may be treated with anti-histamine medications.

As with other medications that act on the immune system, Ustekinumab may increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people.

Ustekinumab may 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. We do not yet know if Ustekinumab increases this risk. However, based on experimental studies and our experience so far – any increase in risk (if at all) with Ustekinumab is likely to be less than 3-4 cases per 10,000 people.

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

Is Ustekinumab safe during pregnancy and breast feeding?

Maternal and paternal use of Ustekinumab 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 Ustekinumab early in the third trimester of your pregnancy. If you are on Ustekinumab 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 Ustekinumab. This has not been shown to have any adverse impact on the baby. It is important to discuss with your provider about continuing Ustekinumab before and during and after pregnancy, but most patients will continue the treatment during their pregnancy.

Health maintenance on Ustekinumab therapy

It is important to be up to date with your health maintenance while on Ustekinumab therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines.

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 Ustekinumab therapy. The manufacturer of Ustekinumab has a patient assistance program for patients on Ustekinumab, called Janssen Carepath. Please go to <https://www.stelara.info.com/crohns-disease/starting-stelara/janssen-carepath> for more information on this program.