Ustekinumab - Medication Information

What is ustekinumab?
Ustekinumab (brand name: Stelara®) is a medication used to treat Crohn’s disease and ulcerative colitis. It is an antibody that blocks inflammation causing proteins in the body.

How is ustekinumab given?
For the first dose, ustekinumab is given into a vein as an infusion. A typical infusion takes 30 minutes.

After the first dose, it is an injection, or shot, that you can give yourself. It comes in a pre-filled syringe. 8 weeks after the infusion, 90 mg is given every 8 weeks. Some patients may need to get the injections more frequently. Your provider will work with you to adjust your injection schedule as needed.

What should I do if I miss a dose of ustekinumab?
Inject your missed dose as soon as you remember, and then give the next injection at the regular scheduled time. If it has been more than 5 days since your injection was due, call your provider for instructions on what to do.

When can I expect ustekinumab to work?
Some patients may feel an improvement in symptoms as soon as 2-3 weeks of starting ustekinumab. Typically, it takes up to 6-8 weeks to notice a significant benefit.

Ustekinumab works for most patients. The medication may stop working in some patients every year. To make sure that it keeps working, it is important to stay on track with your injection schedule and do not miss any injections. In some cases, your doctor may also have you start a second immunosuppressive medication along with ustekinumab to help it work better and to remain effective longer.

Studies have shown that early effective treatment for Crohn’s disease or ulcerative colitis is associated with long-term benefit including lowering the likelihood of needing surgery or hospitalization for health problems related to these conditions.

What tests are needed while I am on ustekinumab?
Before beginning ustekinumab treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood counts and liver tests are done every 4 months while on ustekinumab. At times, your doctor may also check your ustekinumab level to make sure the dose is working well for you.

What are the potential side effects of ustekinumab?
Side effects with ustekinumab are uncommon, but may include:

**Allergic reaction:** Patients may develop allergic reactions to ustekinumab as with any other medication. Reactions may include rash, hives, swelling of the lips or throat. This is uncommon and can be treated with steroid and antihistamine medications.

**Injection site reaction:** Patients may develop an injection site reaction such as pain, redness, or swelling where the injection was given. This is uncommon and may be treated with antihistamine medications.
**Infection:** As with other medications that act on the immune system, ustekinumab may increase your risk of infections. Serious infections are uncommon, but serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.

**Cancer:** Ustekinumab may increase the risk of cancers. The most common is skin cancer, but the risk is very low. The risk may be higher in patients that have pre-existing risk factors for developing skin cancer. It is important to have skin check-ups with dermatology while on ustekinumab.

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

**Is ustekinumab safe during pregnancy and breastfeeding?**
Data shows that ustekinumab during pregnancy is likely safe. Most patients continue the treatment during their pregnancy. If you are pregnant while on ustekinumab, you may get your last dose of the medication early in the 3rd trimester of your pregnancy. Additionally, live virus vaccines such as the rotavirus vaccine are not recommended for your baby within the first 6 months of age. It is safe to breastfeed while on ustekinumab. This has not been shown to have any negative impacts on the baby.

It is important to discuss with your provider about continuing ustekinumab before, during, and after pregnancy.

**How can I take care of my health while on ustekinumab?**
It is important to be up to date with your health maintenance while on ustekinumab. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should only get the recombinant shingles vaccine (brand name: Shingrix®). Do not get the older shingles vaccines that contain the live but weakened virus. You should not get any live vaccines while on ustekinumab or for 3 months after stopping it.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up to date on all your vaccines and cancer screening.

**What if my out-of-pocket costs are high with this treatment?**
Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturer of ustekinumab has a patient assistance program called Janssen Carepath for patients on the medication. Please go to [www.janssencarepath.com/hcp/stelara/affordability](http://www.janssencarepath.com/hcp/stelara/affordability) for more information on this program.

**What if I have questions about ustekinumab?**
Talk with your provider about any questions or concerns you may have about ustekinumab.