



STELARA INFORMED CONSENT FORM

Your physician has recommended an STELARA infusion for your treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the STELARA infusion process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

STELARA is a medication that keeps the immune system from attacking healthy tissues in the body. The immune system also defends the body against infections caused by bacteria and viruses. STELARA interferes with an important step in this attack. By decreasing the immune system's attack on normal tissues, STELARA can reduce pain and joint inflammation.

Indications

STELARA is indicated and FDA approved for the treatment of psoriatic arthritis, plaque psoriasis, and Crohn's disease.

Dosage and Administration

Stelara provides a convenient dosing schedule of 4 times a year after 2 starter doses. Stelara is a 45mg or 90mg injection under the skin as directed by your doctor at 0, 4, and every 12 weeks thereafter. Your health care provider will check your symptoms at all your scheduled appointments while continually reviewing your response to treatment.

A full clinical response may not be evident for several weeks following the infusion. You should continue to take all of your other medications, unless otherwise indicated by your physician.

Potential Adverse Reactions

STELARA is generally well tolerated and most reported reactions are mild to moderate, transient and manageable. The following adverse reactions are the most commonly reported:

- Upper respiratory infection
- Rash
- Fatigue
- Headache

Some more severe side effects have been reported including:

- Serious infection
- Allergic reactions. These reactions are usually mild or moderate, but can be severe.
- The role of STELARA in the development of cancer is not known.
- Reversible posterior leukoencephalopathy syndrome (RPLS) is a very rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS is found early and

treated, most people recover.

Prior to using STELARA, please tell your physician or nurse if you (please initial):

- _____ Have been previously exposed to tuberculosis (TB)
- _____ Have has Hepatitis B or C Infection
- _____ Active cancer
- _____ Pregnant or breast feeding
- _____ Have new symptoms or medical problems
- _____ Have had any live vaccinations recently (These include measles, mumps, rubella, oral polio (the injectable polio vaccine is not live), oral typhoid (typhoid injection is not live), BCG, yellow fever)
- _____ Any Fever or Current Signs/Symptoms of an Infection
- _____ Any Acute Cut, Wound or Rash

I understand all possible side effects from this medication may not have been completely identified and as new information becomes available I will be notified.

I have had the opportunity to fully read, understand and discuss this consent form with my physician and the nurses. By signing this consent, I am agreeing to treatment with STELARA.

Patient's Name

Witness' Name

Patient's Signature

Witness' Signature

Date

Date