

Stelara (ustekinumab)

WHAT IS IT?

Stelara (also known by its generic name ustekinumab) is a biologic medication approved in September of 2009 by the U.S. Food and Drug Administration (FDA). Stelara was approved to treat adult patients 18 years or older with moderate to severe plaque psoriasis. The efficacy and safety of Stelara were evaluated in one of the largest clinical development programs for a biological medication in the treatment of psoriasis.

HOW DOES IT WORK?

Stelara is a human monoclonal antibody that selectively targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23), which are naturally occurring proteins produced by immune cells believed to play a role in psoriasis. By preventing these two proteins from attaching to cells in your body, Stelara improves psoriasis by slowing down the production of skin cells and reducing inflammation.

WHO CAN TAKE IT?

Stelara is prescribed to treat adults 18 years and older with moderate or severe psoriasis that involves large areas, or many areas of their body, and who may be candidates for phototherapy or systemic therapy.

WHO SHOULD NOT TAKE IT?

Patients with active infection, or a history of recurrent infections should not take Stelara. The impact of Stelara on pregnant women or developing fetuses is not known. It is expected that Stelara passes into the breast milk in nursing women, but it is not known if Stelara can pass through the digestive tract and reach the body after ingestion. If you are pregnant or planning to become pregnant, talk to your doctor. Caution is also advised for the elderly, due to the already increased risk of infection for this age group. Stelara is not approved for children.

HOW IS IT USED?

Stelara is given by an injection under the skin at weeks 0 and 4, followed by every-12-week dosing. The recommended starting dose of Stelara is 45 mg for patients weighing 220 lbs. (100 kg) or less, and 90 mg for patients weighing more than 220 lbs. Stelara should only be given by a health care provider as directed by your doctor. Your doctor will choose the exact dose of Stelara for you and decide how often you should receive it.

SIDE EFFECTS

The most common side effects seen in clinical trials were:

- Upper respiratory infection
- Headache
- Tiredness
- Fatigue

These are not all of the possible side effects of Stelara. Tell your doctor about any side effect that bothers you or that does not go away.

EFFECTIVENESS

Psoriasis severity score

- Usually determined by examining the degree of redness, shedding, plaque thickness and affected body surface area. Some scores also take into consideration itching and the disease's effect on quality of life.
- In clinical trials, about 67 percent of patients saw 75 percent improvement in psoriasis severity scores 12 weeks after starting therapy.

RISKS

Stelara is a medicine that affects your immune system. Stelara may increase your chances of having serious side effects, including serious infections and certain types of cancer. Tell your doctor if you have ever had any type of cancer. Some people have developed serious infections while taking Stelara, and some have to be hospitalized for treatment of their infection. Your doctor should check you for tuberculosis (TB) before starting Stelara. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Stelara and during treatment. Your doctor should watch you closely for signs and symptoms of TB during treatment with Stelara.

For detailed information on side effects and safety, talk to your doctor or refer to the medication guide for Stelara.

PATIENT ASSISTANCE INFORMATION:

Centocor Ortho Biotech Inc., which makes Stelara, understands that everyone's financial situation is different. The company's Care Coordinators can help you identify resources that may assist you in reducing your out-of-pocket medication costs. If at any time your insurance or financial situation changes, they can help you find a program that may help keep Stelara affordable.

Stelara Support provides a personal Care Coordinator to help you verify and understand your insurance benefits for Stelara and explain your out-of-pocket costs. If you have any questions, please call 1.877.STELARA (783.5272).

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