MEDICATION GUIDE
STELARA® (stel ar' a)
(ustekinumab)
Injection

Read this Medication Guide before you start taking STELARA® and each time before you get an injection. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment with STELARA®.

What is the most important information I should know about STELARA®?

STELARA® is a medicine that affects your immune system. STELARA® can increase your chances of having serious side effects, including:

Serious Infections: STELARA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have serious infections while taking STELARA®, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses. Some people have to be hospitalized for treatment of their infection.

- Your doctor should check you for 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 with STELARA®.
- Your doctor should watch you closely for signs and symptoms of TB during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA®, tell your doctor if you think you have an infection or have symptoms of an infection such as:

- fever, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in your phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal
- feel very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone who has TB.

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After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above).

STELARA® can make you more likely to get infections or make an infection that you have worse.

People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections. These infections can spread throughout the body and cause death. It is not known if people who take STELARA® will get any of these infections, because of the effects of STELARA® on these proteins in your body.

Cancers:
STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your doctor if you have ever had any type of cancer.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS):
RPLS is a 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. Tell your doctor right away if you have any new or worsening medical problems including:

- headache
- seizures
- confusion
- vision problems

What is STELARA®?

STELARA® is a prescription medicine used to treat adults 18 years and older with moderate or severe psoriasis that involves large areas or many areas of their body, who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).

STELARA® may improve your psoriasis but may also lower the ability of your immune system to fight infections. This may also increase your risk for certain types of cancer.

It is not known if STELARA® is safe and effective in children.

It is not known if taking STELARA® for more than 2 years is safe and effective.

What should I tell my doctor before receiving STELARA®?

Before you receive STELARA®, tell your doctor if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about STELARA®?"
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a vaccine. The viruses used in some types of vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before taking STELARA® or one year after you stop taking STELARA®.**

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- are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with STELARA®. STELARA® may also increase your risk of having an allergic reaction to an allergy shot.
- receive phototherapy for your psoriasis.
- have any other medical conditions.
- are pregnant or planning to become pregnant**.** It is not known if STELARA® will harm your unborn baby. You and your doctor should decide if you will take STELARA®.
- are breast-feeding or plan to breast-feed. It is thought that STELARA® passes into your breast milk. You should not breast-feed while taking STELARA® without first talking with your doctor.
- ever had an allergic reaction to STELARA®. Ask your doctor if you are not sure.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- other medicines that affect your immune system.
- certain medicines that can affect how your liver breaks down other medicines.

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive STELARA®?

- STELARA® is given by injection under the skin (subcutaneous injection).
- STELARA® should only be given by a healthcare provider as directed by your doctor.
- Your doctor will decide the right dose of STELARA® for you and how often you should receive it.
- Be sure to keep all of your scheduled follow-up appointments.

What should I avoid while receiving STELARA®?

You should not receive a live vaccine while taking STELARA®. See "What should I tell my doctor before taking STELARA®?"

What are the possible side effects of STELARA®?

STELARA® can increase your chances of having serious side effects.

- See "**What is the most important information I should know about STELARA®?**"
- **Serious Allergic reactions.** Serious allergic reactions can occur with STELARA®. Get medical help right away if you have any of the following symptoms of a serious allergic reaction:
  - feeling faint
  - swelling of your face, eyelids, tongue, or throat
  - trouble breathing, throat tightness
  - chest tightness

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- skin rash

Common side effects of STELARA® include:

- upper respiratory infections
- headache
- tiredness

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. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Janssen Biotech, Inc. at 1-800-JANSSEN (1-800-526-7736).

General information about STELARA®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about STELARA®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about STELARA® that was written for healthcare professionals.

What are the ingredients in STELARA®?

Active ingredient: ustekinumab

Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, and sucrose.

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403

Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Cilag AG, Schaffhausen, Switzerland

Revised August 2011

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Reference ID: 3111829