A STEP-BY-STEP GUIDE
TO GETTING STARTED WITH STELARA®
What You Can Expect

Now that you and your doctor have decided on STELARA®, it’s time to engage your team, from healthcare provider to specialty pharmacy provider.

The process to obtain STELARA®, a specialty drug, may require different steps from your previous treatment. The Case Coordinators at StelaraSupport™ are part of your team that provides personalized assistance during each stage of the process, to help you get the most out of managing your treatment.

Call StelaraSupport™ at 1-877-STELARA (1-877-783-5272), Monday through Friday, 8 AM to 8 PM ET.

For Your Records

Name of specialty pharmacy

Date of first dose

Specialty pharmacy phone number

Doctor’s office phone number

Office Staff/Biologics Coordinator

Selected Safety Information

STELARA® is not for everyone; only your doctor can decide if it’s right for you. STELARA® is a prescription medicine that affects your immune system. It can increase your chances of having serious side effects including infections, cancer, serious allergic reactions and a rare condition called reversible posterior leukoencephalopathy syndrome. Please read the Important Safety Information on pages 10–12 of this brochure and the enclosed Medication Guide for STELARA® to learn more about these and other risks for STELARA®. Discuss any questions you have with your doctor.
Three Steps To STELARA®

As a patient, you are an integral part of your team. These steps outline the process and identify when you can assist in the management of your treatment.

**STEP 1**

Check Insurance Benefits

**STEP 2**

Pay As Little As $5 A Dose*

**STEP 3**

Start On Your Treatment Schedule

*Eligibility restrictions apply

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Your Team

Many people work together to get your treatment to you.

1. **HEALTHCARE PROVIDER:** Assesses your condition and decides which treatment is best for you

2. **OFFICE COORDINATOR:** Works as part of your doctor’s staff to ensure your insurance is verified and that the pharmacy successfully receives your STELARA® prescription

3. **SPECIALTY PHARMACY PROVIDER:** Receives your prescription from your doctor and works in these three ways:
   - **Coverage:** Helps you get insurance authorization through your pharmacy and/or medical benefits
   - **Affordability:** Makes sure you can afford the treatment by applying your Instant Savings Co-Pay Card to your out-of-pocket expenses
   - **Delivery:** Handles shipping details to make sure you receive your dose on time, every time

4. **STELARASUPPORT™ CASE COORDINATOR:** Provides personalized assistance during each stage of the process, to help you get the most out of managing your treatment whenever you need it

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STEP 1: Check Insurance Benefits
To Make Sure You’re Covered

Remind the doctor’s staff and the specialty pharmacy to investigate both pharmacy and medical benefits. You can also contact a Case Coordinator to assist you with your benefits investigation. Call StelaraSupport™ at 1-877-STELARA (1-877-783-5272), Monday through Friday, 8 AM to 8 PM ET.

Did you know STELARA® can be covered in 2 ways: through your pharmacy and/or medical benefits? Coverage for your biologic medicine typically depends on how your treatment is given.

**PHARMACY BENEFITS** provide coverage for medicine you inject at home, after training.

**MEDICAL BENEFITS** provide coverage for injections by a medical professional at a doctor’s office.

Since STELARA® is a prescription drug that can be administered two ways, the treatment can be covered by either insurance benefit.

If your doctor’s staff or specialty pharmacy says that you’re not covered, make sure to ask them if they’ve checked both benefits. Don’t assume that your medical benefits have been checked. (Since STELARA® is an injection that may be given at the office, your medication may be covered by your medical benefits.)

Please note it may take several days for your coverage to be checked and approved by your insurance carrier. Once approved, the specialty pharmacy (or in some cases the doctor’s office) will call you to inform you of your coverage.

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STEP 2: Learn About Medication Savings & Pay As Little As $5 A Dose*

While you are awaiting the approval of your benefits, activate your Instant Savings Co-Pay Card to earn savings on your prescription today by calling 1-877-STELARA (1-877-783-5272).

We offer the StelaraSupport™ Instant Savings Program to help save on out-of-pocket costs such as co-pay assistance. Once enrolled, you may be eligible for automatic re-enrollment in the savings program each year.

You can also work with a StelaraSupport™ Case Coordinator or your Specialty Pharmacy to save money. To learn about other financial options, call StelaraSupport™ at 1-877-STELARA (1-877-783-5272) or visit STELARAINfo.com.

If you do not have insurance coverage for STELARA®, Janssen Prescription Assistance may be able to help. This program offers information about independent foundations that may have available funding to help lessen drug costs for STELARA®.
STEP 3: Start On Your Treatment Schedule

( the steps to get to your first dose )

A) Order Dose

When the specialty pharmacy calls you, provide them with your payment information, your Instant Savings Co-Pay Card number (if applicable), and confirm the delivery location and timing of your delivery.

Once your insurance benefits have been approved, expect a welcome call from the specialty pharmacy, informing you of your coverage, notifying you of your out-of-pocket costs, and to begin the ordering process.

B) Schedule Dose

Once the delivery timing of your first dose has been confirmed with the specialty pharmacy, ensure you have an appointment with your doctor to receive your first dose (a couple days after your prescription is scheduled to be delivered).

STELARA® can be delivered to your home or doctor’s office (your doctor will indicate where it should be delivered). If it is shipped to your home, follow the directions on how to store and transport the medication.

The specialty pharmacy will work with the doctor’s office to confirm shipment. Please note your first dose will always be given at the doctor’s office.

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Continue on STELARA® (the steps for your future doses)

Your doctor will decide if your second starter dose and your maintenance doses will be given at the doctor’s office or if you can self-administer at home. If you are self-administering, check out our Injection Support page for tools and resources at STELARAinfo.com/self-injection.

If your doctor decided that you or a caregiver may give your injections at home, you should get training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® until properly trained by a healthcare provider. Please read the “Instructions for Use” to learn how to prepare and inject STELARA,® and how to properly throw away used syringes at STELARAinfo.com.

The specialty pharmacy will call you to re-order your dose. If you have not heard from them one week prior to your next scheduled dose, please call them directly to place the order. If you are not self-injecting, make an appointment with your doctor’s office to schedule the next administration of your dose.

Stay Committed To The Treatment Plan

You and your doctor have chosen STELARA® as a treatment. As you continue on your journey, it’s important for you to stay on your medication schedule as your doctor prescribed in order to see results.

Your team is here to help you. Call StelaraSupport™ at 1-877-STELARA (1-877-783-5272), Monday through Friday, 8 AM to 8 PM ET with any questions. Please inform the doctor’s office and the specialty pharmacy if your insurance coverage or delivery address for your prescription changes.

Now that you’re a STELARA® patient, take full advantage of all the support services we offer, by signing up for StelaraSupport™. Sign up at STELARAinfo.com or call 1-877-STELARA (1-877-783-5272).

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Summary Of A Step-By-Step Guide To STELARA®

STEP 1: Check Insurance Benefits To Make Sure You’re Covered
Remind the doctor’s staff to investigate both medical and pharmacy benefits before leaving the office

STEP 2: Learn About Medication Savings & Pay As Little As $5 A Dose*
Check your eligibility and activate your Instant Savings Co-Pay Card at STELARAinfo.com or call StelaraSupport™ for other financial options

STEP 3: Start On Your Treatment Schedule
(the steps to get to your first dose)
A. Order Dose With The Specialty Pharmacy
B. Schedule Dose At The Doctor’s Office

Continue On STELARA® And Stay Committed To The Treatment Plan
As you continue on your journey, it’s important for you to stay on your medication schedule as your doctor prescribed in order to see results.

Your team is here to help you. Call StelaraSupport™ at 1-877-STELARA (1-877-783-5272) with any questions.

Please read the Important Safety Information enclosed in this brochure and the enclosed Medication Guide for STELARA®. Discuss any questions you have with your doctor.

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Selected Safety Information
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IMPORTANT SAFETY INFORMATION

STELARA® (ustekinumab) is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

**Serious Infections**

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®
- If your doctor feels that you are at risk for TB, you may be treated for TB before and 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

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 that 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.

**Cancers**

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your doctor if you have any new skin growths.

**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, and vision problems.

**Serious Allergic Reactions**

Serious allergic reactions can occur. Get medical help right away if you have any symptoms such as: feeling faint, swelling of your face, eyelids, tongue, or throat, trouble breathing, throat or chest tightness, or skin rash.

Continued on next page
Continued from previous page

Before receiving STELARA®, tell your doctor if you:

• have any of the conditions or symptoms listed above for serious infections, cancers, or RPLS
• ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor if you are not sure.
• are allergic to latex. The needle cover on the prefilled syringe contains latex.
• 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®.
• have any new or changing lesions within psoriasis areas or on normal skin
• are receiving or have received allergy shots, especially for serious allergic reactions
• receive or have received phototherapy for your psoriasis
• have any other medical conditions
• are pregnant or plan 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 to your doctor.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

When prescribed STELARA®:

• Use STELARA® exactly as prescribed by your doctor
• If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® yourself until you or your caregiver has been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: upper respiratory infections, headache, tiredness, joint pain, and nausea. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please read the full Prescribing Information, including the Medication Guide for STELARA®, and discuss any questions you have with your doctor.
STELARA® is administered by subcutaneous injection. (2)

Psoriasis

- For patients weighing ≤100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. (2.1)
- For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. (2.1)

Psoriatic Arthritis

- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. (2.1)
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. (2.1)

Warnings and Precautions, Concomitant Therapies (5.8) 03/2014

- Injection:
  - Injection: 45 mg/0.5 mL in a single-use prefilled syringe (3)
  - Injection: 90 mg/mL in a single-use prefilled syringe (3)

- Injection: 45 mg/0.5 mL in a single-use vial (3)
- Injection: 90 mg/mL in a single-use vial (3)

- Live vaccines: Live vaccines should not be given with STELARA®. (7.1)
- Concomitant therapy: In psoriasis studies, the safety of concomitant use of STELARA® with immunosuppressants or phototherapy has not been evaluated. (7.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Psoriasis (Ps)

STELARA® is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

1.2 Psoriatic Arthritis (PsA)

STELARA® is indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. STELARA® can be used alone or in combination with methotrexate (MTX).

2 DOSAGE AND ADMINISTRATION

2.1 Dosing

STELARA® is administered by subcutaneous injection.

Psoriasis

- For patients weighing <100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Psoriatic Arthritis

- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

In subjects weighing >100 kg, 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these subjects (see Clinical Studies (14)).

2.2 General Considerations for Administration

STELARA® is for subcutaneous administration. STELARA® is intended for use under the guidance and supervision of a physician. STELARA® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

After proper training in subcutaneous injection technique, a patient may self inject with STELARA® if a physician determines that it is appropriate. Patients should be instructed to follow the directions provided in the Medication Guide (see Medication Guide).

Prior to administration, STELARA® should be visually inspected for particulate matter and discoloration. STELARA® is colorless to slightly yellow and may contain a few small translucent or white particles. STELARA® should not be used if it is discolored or cloudy, or if other particulate matter is present. STELARA® does not contain preservatives; therefore, any unused product remaining in the vial and/or syringe should be discarded.

The needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex). The needle cover should not be handled by persons sensitive to latex. The needle cover should not be handled by persons sensitive to latex. The needle cover should not be handled by persons sensitive to latex. It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated. When using the single-use vial, a 27 gauge, ½ inch needle is recommended.

2.3 Instructions for Administration of STELARA® Prefilled Syringes Equipped with Needle Safety Guard

Refer to the diagram below for the provided instructions.

To prevent premature activation of the needle safety guard, do not touch the NEEDLE GUARD ACTIVATION CLIPS at any time during use.

- Hold the BODY and remove the NEEDLE COVER. Do not hold the PLUNGER or PLUNGER HEAD while removing the NEEDLE COVER or the PLUNGER may move. Do not use the prefilled syringe if it is dropped without the NEEDLE COVER in place.
- Inject STELARA® subcutaneously as recommended (see Dosage and Administration [2.2]).

STELARA® (ustekinumab)

- Inject all of the medication by pushing in the PLUNGER until the PLUNGER HEAD is completely between the needle guard wings. Injection of the entire prefilled syringe contents is necessary to activate the needle guard.

- After injection, maintain the pressure on the PLUNGER HEAD and remove the needle from the skin. Slowly take your thumb off the PLUNGER HEAD to allow the empty syringe to move up until the entire needle is covered by the needle guard, as shown by the illustration below:

- Used syringes should be placed in a puncture-resistant container.

3 DOSAGE FORMS AND STRENGTHS

STELARA® solution is colorless to slightly yellow in appearance and contains 90 mg ustekinumab per mL.

- Injection: 45 mg/0.5 mL in a single-use prefilled syringe
- Injection: 90 mg/mL in a single-use prefilled syringe
- Injection: 45 mg/0.5 mL in a single-use vial
- Injection: 90 mg/mL in a single-use vial

4 CONTRAINDICATIONS

Clinically significant hypersensitivity to ustekinumab or to any of the excipients (see Warnings and Precautions [5.5]).

5 WARNINGS AND PRECAUTIONS

5.1 Infections

STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were observed in subjects receiving STELARA® (see Adverse Reactions [6.1]).

STELARA® should not be given to patients with any clinically important active infection. STELARA® should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering the use of STELARA® in patients with a chronic infection or a history of recurrent infection.

Serious infections requiring hospitalization occurred in the psoriasis and psoriatic arthritis development programs. In the psoriasis program, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In the psoriatic arthritis program, serious infections included cholecystitis.

5.2 Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), salmonella (including nontyphi strains), and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients.

It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® will be susceptible to these types of infections. Appropriate diagnostic testing should be considered, e.g., tissue culture, stool culture, as dictated by clinical circumstances.

5.3 Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis infection prior to initiating treatment with STELARA®.

Do not administer STELARA® to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering STELARA®. Consider anti-tuberculosis therapy prior to initiation of STELARA® in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving STELARA® should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

5.4 Malignancies

STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among subjects who received STELARA® in clinical studies (see Adverse Reactions [6.1]). In rodent models, inhibition of IL-12/IL-23p40 increased the risk of malignancy (see Nonclinical Toxicology [13]).

The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

There have been post marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had...
5.5 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported. If a hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA® [see Adverse Reactions (6.3)].

6.3 Post-marketing Experience

Adverse reactions that occurred at rates less than 1% in the controlled period of Ps STUDIES 1 and 2 through week 12 included: cellulitis, herpes zoster, diverticulitis and certain injection site reactions (pain, swelling, pruritus, induration, hemorrhage, bruising, and irritation).

One case of RPLS occurred during clinical trials [see Warnings and Precautions (5.6)].

Infections

The placebo-controlled period of clinical studies of psoriasis subjects (average follow-up of 12.6 weeks for placebo-treated subjects and 13.4 weeks for STELARA®-treated subjects), 27% of STELARA®-treated subjects reported infections (1.39 per subject-year of follow-up) compared with 24% of placebo-treated subjects (1.21 per subject-year of follow-up). Serious infections occurred in 0.3% of STELARA®-treated subjects (0.01 per subject-year of follow-up) and in 0.4% of placebo-treated subjects (0.02 per subject-year of follow-up) [see Warnings and Precautions (5.4)].

In the controlled and non-controlled portions of psoriasis clinical trials (median follow-up of 3.2 years), representing 8998 subject-years of exposure, 72.3% of STELARA®-treated subjects reported infections (0.87 per subject-years of follow-up). Serious infections were reported in 2.8% of subjects (0.01 per subject-years of follow-up).

Malignancies

In an open-label, non-controlled portion of psoriasis clinical trials (median follow up of 3.2 years, representing 8998 subject-years of exposure), 1.7% of STELARA®-treated subjects reported malignancies excluding non-melanoma skin cancers (0.60 per hundred subject-years of follow-up). Non-melanoma skin cancer was reported in 1.5% of STELARA®-treated subjects (0.52 per hundred subject-years of follow-up) [see Warnings and Precautions (5.4)]. The most frequently observed malignancies other than non-melanoma skin cancer during the clinical trials were: prostate, melanoma, colorectal and breast. Malignancies other than non-melanoma skin cancer in STELARA®-treated patients during the controlled and uncontrolled portions of studies were similar in type and number to what would be expected in the general U.S. population according to the SEER database (adjusted for age, gender, and race).

Psoriatic Arthritis Clinical Studies

The safety of STELARA® was assessed in 927 patients in two randomized, double-blind, placebo-controlled studies in adult patients with active psoriatic arthritis (PsA). The overall safety profile of STELARA® in patients with PsA was consistent with the safety profile seen in psoriasis clinical studies. A higher incidence of arthropalgia, nausea, and dental infections was observed in STELARA®-treated patients when compared with placebo-treated patients (3% vs. 1% for arthropalgia and 3% vs. 1% for nausea; 1% vs. 0.6% for dental infections) in the placebo-controlled portions of the PsA clinical trials.

6.2 Immune System Disorders

Approximately 6% of patients treated with STELARA® in psoriasis and psoriatic arthritis clinical studies developed antibodies to ustekinumab, which were generally low-titer. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was seen. No ustekinumab-related serious hypersensitivity reactions were observed in psoriasis and psoriatic arthritis clinical trials. In psoriasis studies, the majority of patients who were positive for antibodies to ustekinumab had neutralizing antibodies. The data above reflect the percentage of subjects whose test results were positive for antibodies to ustekinumab and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons, comparison of the incidence of antibodies to ustekinumab with the incidence of antibodies to other products may be misleading.

6.3 Post-marketing Experience

Adverse reactions have been reported during post-approval use with STELARA®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to STELARA® exposure.

Immune system disorders: Serious hypersensitivity reactions (including anaphylaxis and angioedema), other hypersensitivity reactions (including rash and urticaria).

Skin reactions: Pustular psoriasis, erythrodema psoriasis.

7. DRUG INTERACTIONS

Drug interaction studies have not been conducted with STELARA®.

7.1 Live Vaccines

Live vaccines should not be given concurrently with STELARA® [see Warnings and Precautions (5.7)].

7.2 Concomitant Therapies

In psoriasis studies the safety of STELARA® in combination with immunosuppressive agents or phototherapy has not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA® [see Warnings and Precautions (5.5)].
7.3 CYP450 Substrates

The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, IFN) during chronic inflammation. Thus, STELARATHM, an antagonist of IL-12 and IL-23, could normalize the formation of CYP450 enzymes. Upon initiation of STELARATHM in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, monitoring for therapeutic effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) should be considered and the individual dose of the drug adjusted as needed (see Clinical Pharmacology (12.3)).

7.4 Allergen Immunotherapy

STELARATHM has not been evaluated in patients who have undergone allergen immunotherapy. STELARATHM may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B

Pregnancy Registry

There is a pregnancy registry that monitors pregnancy outcomes in women exposed to STELARATHM during pregnancy. Patients should be encouraged to enroll by calling 1-877-311-8972.

There are no adequate and well controlled studies of STELARATHM in pregnant women. Developmental toxicity studies conducted with monkeys found no evidence of harm to the fetus due to ustekinumab. STELARATHM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Ustekinumab was tested in two embryo-fetal development toxicity studies with cynomolgus monkeys. No teratogenic effects or other adverse developmental effects were observed in fetuses from pregnant monkeys that were administered ustekinumab during the period of organogenesis either twice weekly via subcutaneous injections or weekly by intravenous injections at doses up to 45 times the maximum recommended human dose (MRHD) (on a mg/kg basis at a maternal dose of 45 mg/kg).

In a combined embryo-fetal development and pre- and post-natal development toxicity study, pregnant cynomolgus monkeys were administered subcutaneous doses of ustekinumab twice weekly up to 45 times the MRHD (on a mg/kg basis at a maternal dose of 45 mg/kg) from the beginning of organogenesis to Day 33 after delivery. Neonatal deaths occurred in the offspring of one monkey administered ustekinumab at 22.5 mg/kg and one monkey dosed at 45 mg/kg. No ustekinumab-related effects on functional, morphological, or immunological development were observed in the neonates from birth through six months of age.

8.3 Nursing Mothers

Caution should be exercised when STELARATHM is administered to a nursing woman.

The unknown risks to the infant from gastrointestinal or systemic exposure to ustekinumab should be weighed against the known benefits of breast-feeding. Ustekinumab should be present in human milk, so it is expected that STELARATHM will be present in human milk. It is not known if ustekinumab is absorbed systemically after ingestion; however, published data suggest that antibodies in breast milk do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use

Safety and effectiveness of STELARATHM in pediatric patients have not been evaluated.

8.5 Geriatric Use

Of the 4031 subjects exposed to STELARATHM, a total of 248 were 65 years or older (183 patients with psoriasis and 65 patients with psoriatic arthritis), and 29 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects.

10 OVERDOSAGE

Single doses up to 6 mg/kg intravenously have been administered in clinical studies without dose-limiting toxicity. In case of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately.

11 DESCRIPTION

STELARATHM is a human IgG1x monoclonal antibody against the p40 subunit of the IL-12 and IL-23 cytokines. Using DNA recombinant technology, STELARATHM is produced in a well characterized recombinant cell line and is purified using standard bioprocessing technology. The manufacturing process contains steps for the clearance of viruses. STELARATHM is comprised of 1326 amino acids and has an estimated molecular mass that ranges from 148,079 to 149,690 Daltons.

STELARATHM, for subcutaneous use, is available as: 45 mg of ustekinumab in 0.5 mL and 90 mg of ustekinumab in 1 mL. STELARATHM is supplied as a sterile solution in a single-use prefilled syringe with a 27 gauge fixed 1/2 inch needle, or a single-use 2 mL Type I glass vial with a coated stopper. The syringe is fitted with a passive needle guard and a needle cover that is manufactured using a dry natural rubber (a derivative of latex).

Each 45 mg ustekinumab prefilled syringe also contains: L-histidine and L-histidine monohydrochloride monohydrate (0.5 mg), Polysorbate 80 (0.02 mg), and sucrose (38 mg) to fill to a final volume of 0.5 mL.

Each 90 mg ustekinumab prefilled syringe also contains: L-histidine and L-histidine monohydrochloride monohydrate (1 mg), Polysorbate 80 (0.04 mg), and sucrose (76 mg) to fill to a final volume of 1 mL.

Each 45 mg ustekinumab vial also contains: L-histidine and L-histidine monohydrochloride monohydrate (0.5 mg), Polysorbate 80 (0.02 mg), and sucrose (38 mg) to fill to a final volume of 0.5 mL.

Each 90 mg ustekinumab vial also contains: L-histidine and L-histidine monohydrochloride monohydrate (1 mg), Polysorbate 80 (0.04 mg), and sucrose (76 mg) to fill to a final volume of 1 mL.

The STELARATHM solution is colorless to slightly yellow in appearance and has a pH of 5.7-6.3. STELARATHM does not contain preservatives.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Ustekinumab is a human IgG1x monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune response such as natural killer cell activation and CD4+ T-cell differentiation and activation. In in vitro models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12Rb1.

12.2 Pharmacodynamics

In a small exploratory study, a decrease was observed in the expression of mRNA of its molecular targets IL-12 and IL-23 in lesional skin biopsies measured at baseline and up to two weeks post-treatment in subjects with psoriasis.

12.3 Pharmacokinetics

Absorption

In subjects with psoriasis, the median time to reach the maximum serum concentration (Tmax) was 13.5 days and 7 days, respectively, after a single subcutaneous administration of 45 mg (N=22) and 90 mg (N=24) of ustekinumab. In healthy subjects (N=30), the median Tmax value (8.5 days) following a single subcutaneous administration of 90 mg of ustekinumab was comparable to that observed in subjects with psoriasis. Following multiple subcutaneous doses of STELARATHM, the steady-state serum concentrations of ustekinumab were achieved by Week 28. The mean (±SD) steady-state trough serum concentration ranged from 0.31 ± 0.33 mcg/mL (45 mg) to 0.64 ± 0.64 mcg/mL (90 mg). There was no apparent accumulation in serum ustekinumab concentration over time when given subcutaneously every 2 weeks.

Distribution

Following subcutaneous administration of 45 mg (N=18) and 90 mg (N=21) of ustekinumab to subjects with psoriasis, the mean (±SD) apparent volume of distribution during the terminal phase (Vz/F) was 161 ± 65 mL/kg and 179 ± 85 mL/kg, respectively. The mean (±SD) volume of distribution during the terminal phase (Vz) following a single intravenous administration to subjects with psoriasis ranged from 56.1 ± 6.5 to 82.1 ± 23.6 mL/kg.

Metabolism

The metabolic pathway of ustekinumab has not been characterized. As a human IgG1x monoclonal antibody ustekinumab is expected to be degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG.

Elimination

The mean (±SD) systemic clearance (CL) following a single intravenous administration of ustekinumab to subjects with psoriasis ranged from 1.90 ± 0.28 to 2.22 ± 0.63 mL/day/kg. The mean (±SD) half-life ranged from 14.9 ± 4.6 to 45.6 ± 80.2 days across all psoriasis studies following intravenous and subcutaneous administration.

Weight

When given the same dose, subjects with psoriasis or psoriatic arthritis weighing >100 kg had lower median serum ustekinumab concentrations compared with those subjects weighing ≤100 kg. The median trough serum concentrations of ustekinumab in subjects of higher weight (≥100 kg) in the 90 mg group were comparable to those in subjects of lower weight (≤100 kg) in the 45 mg group.
**STELARA® (ustekinumab)**

**Hepatic and Renal Impairment**

No pharmacokinetic data are available in patients with hepatic or renal impairment.

**Elderly**

A population pharmacokinetic analysis (N=106/1937 subjects greater than or equal to 65 years old) was performed to evaluate the effect of age on the pharmacokinetics of ustekinumab. There were no apparent changes in pharmacokinetic parameters (clearance and volume of distribution) in subjects older than 65 years old.

**Drug-Drug Interactions**

The effects of IL-12 or IL-23 on the regulation of CYP450 enzymes were evaluated in an in vitro study using human hepatocytes, which showed that IL-12 and/or IL-23 at levels of 10 ng/mL did not alter human CYP450 enzyme activities (CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4). However, the clinical relevance of in vitro data has not been established [see Drug Interactions (7.3)].

Population pharmacokinetic data analyses indicated that the clearance of ustekinumab was not impacted by concomitant MTX, NSAIDs, and oral corticosteroids, or prior exposure to anti-TNFα agents in patients with psoriatic arthritis.

### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to evaluate the carcinogenic or mutagenic potential of STELARA®. Published literature showed that administration of murine IL-12 caused an anti-tumor effect in mice that contained transplanted tumors and IL-12(IL-23p40) knockout mice or mice treated with anti-IL-12/IL-23p40 antibody had decreased host defense to tumors. Mice genetically manipulated to be deficient in both IL-12 and IL-23 or IL-12 alone showed decreased host defense to tumors. The relevance of these experimental findings in mouse models for malignancy risk in humans is unknown.

No effects on fertility were observed in male cynomolgus monkeys that were administered ustekinumab at subcutaneous doses up to 45 mg/kg twice weekly (45 times the MRHD on a mg/kg basis) prior to and during the mating period. However, fertility and pregnancy outcomes were not evaluated in mated females.

No effects on fertility were observed in female mice that were administered an analogous IL-12/IL-23p40 antibody by subcutaneous administration at doses up to 50 mg/kg, twice weekly, prior to and during early pregnancy.

#### 13.2 Animal Toxicology and/or Pharmacology

In a 26-week toxicology study, one out of 10 monkeys subcutaneously administered 45 mg/kg ustekinumab twice weekly for 26 weeks had a bacterial infection.

### 14 CLINICAL STUDIES

#### 14.1 Psoriasis

Two multicenter, randomized, double-blind, placebo-controlled studies (Ps STUDY 1 and Ps STUDY 2) enrolled a total of 1996 subjects 18 years of age and older with plaque psoriasis who had a minimum body surface area involvement of 10%, and Psoriasis Area and Severity Index (PASI) score ≥12, and who were candidates for treatment with STELARA®. Subjects randomized to treatment withdrawal were re-randomized at Week 40 to either continued dosing of STELARA® or placebo (treatment withdrawal after Week 28 dose). The median time to loss of PASI 75 response among the subjects randomized to treatment withdrawal was 16 weeks.

#### 14.2 Psoriatic Arthritis

The safety and efficacy of STELARA® was assessed in 927 patients (PsA STUDY 1, n=615; PsA STUDY 2, n=312), in two randomized, double-blind, placebo-controlled studies in adult patients 18 years of age and older with active PsA (≥5 swollen joints and ≥5 tender joints) despite non-steroidal anti-inflammatory (NSAID) or disease modifying antirheumatic (DMARD) therapy. Patients in these studies had a diagnosis of PsA for at least 6 months. Patients with each subtype of PsA were enrolled, including polyarticular arthritis with the absence of rheumatoid nodules (39%), spondylitis with peripheral arthritis (28%), asymmetric peripheral arthritis (21%), distal interphalangeal involvement (12%) and arthritis mutilans (0.5%). Over 70% and 40% of the patients, respectively, had enthesitis and dactylitis at baseline.

Patients were randomized to receive treatment with STELARA® 45 mg, 90 mg, or placebo subcutaneously at Weeks 0 and 4 followed by every 12 weeks (q12w) dosing. Approximately 50% of patients continued on stable doses of MTX (<25 mg/week). The primary endpoint was the percentage of patients achieving ACR 20 response at Week 24.

In PsA STUDY 1 and PsA STUDY 2, 80% and 86% of the patients, respectively, had been previously treated with DMARDs. In PsA STUDY 1, previous treatment with anti-tumor necrosis factor (TNF)-α agent was not allowed. In PsA STUDY 2, 58% (n=180) of the patients had been previously treated with an anti-TNFα agent, of whom over 70% had discontinued their anti-TNFα treatment for lack of efficacy or intolerance at any time.

**Clinical Response**

In both studies, a greater proportion of patients achieved ACR 20, ACR 50 and PASI 75 response in the STELARA® 45 mg and 90 mg groups compared to placebo at Week 24 (see Table 4). ACR 70 responses were also higher in the STELARA® 45 mg and 90 mg groups, although the difference was only numerical (p=NS) in Study 2. Responses were similar in patients regardless of prior TNFα exposure.
Table 4. ACR 20, ACR 50, ACR 70 and PASI 75 responses in PsA STUDY 1 and PsA STUDY 2 at Week 24

<table>
<thead>
<tr>
<th></th>
<th>PsA STUDY 1</th>
<th>PsA STUDY 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo</td>
<td>45 mg</td>
</tr>
<tr>
<td>Number of patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>randomized</td>
<td>206</td>
<td>205</td>
</tr>
<tr>
<td>ACR 20 response, N(%)</td>
<td>47 (22%)</td>
<td>87 (42%)</td>
</tr>
<tr>
<td>ACR 50 response, N(%)</td>
<td>18 (9%)</td>
<td>51 (25%)</td>
</tr>
<tr>
<td>ACR 70 response, N(%)</td>
<td>5 (2%)</td>
<td>25 (12%)</td>
</tr>
<tr>
<td>Number of patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>with ≥3% BSAa</td>
<td>146</td>
<td>145</td>
</tr>
<tr>
<td>PASI 75 response, N(%)</td>
<td>16 (11%)</td>
<td>83 (57%)</td>
</tr>
</tbody>
</table>

a Number of patients with ≥3% BSA psoriasis skin involvement at baseline

The percent of patients achieving ACR 20 responses by visit is shown in Figure 1.

Figure 1: Percent of patients achieving ACR 20 response through Week 24

The results of the components of the ACR response criteria are shown in Table 5.

Table 5. Mean change from baseline in ACR components at Week 24

<table>
<thead>
<tr>
<th></th>
<th>PsA STUDY 1</th>
<th>STELARA®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo</td>
<td>45 mg</td>
</tr>
<tr>
<td>Number of swollen jointsa</td>
<td>N=206</td>
<td>N=205</td>
</tr>
<tr>
<td>Baseline</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-3</td>
<td>-5</td>
</tr>
<tr>
<td>Number of tender jointsb</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>25</td>
<td>22</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-4</td>
<td>-8</td>
</tr>
<tr>
<td>Patient’s assessment of painc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6.1</td>
<td>6.2</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-0.5</td>
<td>-2.0</td>
</tr>
<tr>
<td>Patient global assessmentc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6.1</td>
<td>6.3</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-0.5</td>
<td>-2.0</td>
</tr>
<tr>
<td>Physician global assessmentc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>5.8</td>
<td>5.7</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-1.4</td>
<td>-2.6</td>
</tr>
<tr>
<td>Disability index (HAQ)d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-0.1</td>
<td>-0.3</td>
</tr>
<tr>
<td>CRP (mg/dL)e</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.6</td>
<td>1.7</td>
</tr>
<tr>
<td>Mean Change at Week 24</td>
<td>-0.015</td>
<td>-0.5</td>
</tr>
</tbody>
</table>

a Number of swollen joints counted (0-66)
b Number of tender joints counted (0-68)
c Visual analogue scale; 0= best, 10=worst.
d Disability Index of the Health Assessment Questionnaire; 0 = best, 3 = worst, measures the patient’s ability to perform the following: dress/groom, arise, eat, walk, reach, grip, maintain hygiene, and maintain daily activity.
e CRP: (Normal Range 0.0-1.0 mg/dL)

An improvement in enthesitis and dactylitis scores was observed in each STELARA® group compared with placebo at Week 24.

15 REFERENCES


16 HOW SUPPLIED/STORAGE AND HANDLING

STELARA® does not contain preservatives. STELARA® is available in single-use prefilled syringes or single-use vials containing 45 mg or 90 mg of ustekinumab. Each prefilled syringe is equipped with a needle safety guard.

The NDC number for the 45 mg prefilled syringe is 57894-060-03.
The NDC number for the 90 mg prefilled syringe is 57894-061-03.
The NDC number for the 45 mg vial is 57894-060-02.
The NDC number for the 90 mg vial is 57894-061-02.

Storage and Stability

STELARA® vials and prefilled syringes must be refrigerated at 2°C to 8°C (36°F to 46°F). Store STELARA® vials upright. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. STELARA® does not contain a preservative; discard any unused portion.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide and Instructions for Use) Instruct patients to read the Medication Guide before starting STELARA® therapy and to reread the Medication Guide each time the prescription is renewed.

Infections

Inform patients that STELARA® may lower the ability of their immune system to fight infections. Instruct patients of the importance of communicating any history of infections to the doctor, and contacting their doctor if they develop any symptoms of infection.

Malignancies

Patients should be counseled about the risk of malignancies while receiving STELARA®.

Allergic Reactions

Advise patients to seek immediate medical attention if they experience any symptoms of serious allergic reactions.

17.1 Instruction on Injection Technique

The first self-injection should be performed under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer STELARA®, he/she should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of STELARA® [see Medication Guide and Instructions for Use].

Patients should be instructed to inject the full amount of STELARA® according to the directions provided in the Medication Guide and Instructions for Use. The needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Needles and syringes should be disposed of in a puncture-resistant container. Patients or caregivers should be instructed in the technique of proper syringe and needle disposal, and be advised not to reuse these items.

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403 and at Cilag AG, Schaffhausen, Switzerland

MEDICATION GUIDE
STELARA® (ustekinumab)
Injection

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

STELARA® is a medicine that affects your immune system. STELARA® can increase your risk 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.

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. Some people who are receiving STELARA® and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with STELARA®, tell your doctor if you develop any new skin growths.

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:

- active psoriatic arthritis. STELARA® can be used alone or with methotrexate.

STELARA® may improve your psoriasis and psoriatic arthritis 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.

Who should not take STELARA®?

Do not take STELARA® if you are allergic to ustekinumab or any of the ingredients in STELARA®. See the end of this Medication Guide for a complete list of ingredients in STELARA®.

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 ever had an allergic reaction to STELARA®. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- 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®.
- have any new or changing lesions within psoriasis areas or on normal skin.
- 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 or have received 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®. There is a pregnancy registry for women who take STELARA® during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you are pregnant or become pregnant while taking STELARA®, talk to your doctor about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

• 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.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use STELARA®?
• Use STELARA® exactly as prescribed by your doctor.
• If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.
• STELARA® is given by injection under the skin (subcutaneous injection), in your upper arms, buttocks, upper legs (thighs) or stomach area (abdomen).
• Do not give an injection in an area of the skin that is tender, bruised, red or hard.
• Use a different injection site each time you use STELARA®.
• If you inject more STELARA® than prescribed, call your doctor right away.
• Be sure to keep all of your scheduled follow-up appointments.
• Read the detailed Instructions for Use at the end of this Medication Guide for instructions about how to prepare and inject a dose of STELARA®, and how to properly throw away (dispose of) used needles and syringes.

What should I avoid while using STELARA®?
You should not receive a live vaccine while taking STELARA®. See “What should I tell my doctor before receiving STELARA®?”

What are the possible side effects of STELARA®?
STELARA® may cause serious side effects, including:
• 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
  • 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).

How do I store STELARA®?
• Store STELARA® in a refrigerator, between 36ºF to 46ºF (2ºC to 8ºC) in the original carton until it is used.
• Store STELARA® vials upright.
• Protect from light.
• Do not freeze STELARA®.
• Do not shake STELARA®.
• Throw away (dispose of) any unused STELARA®.

Keep STELARA® and all medicines out of the reach of children.

General information about STELARA®
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STELARA® for a condition for which it was not prescribed. Do not give STELARA® to other people, even if they have the same symptoms that you have. It may harm them.

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 health professionals.

What are the ingredients in STELARA®?
Active ingredient: ustekinumab
Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, and sucrose.

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

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403 and at Cilag AG, Schaffhausen, Switzerland
Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Cilag AG, Schaffhausen, Switzerland

Revised 03/2014
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INSTRUCTIONS FOR USE
STELARA® (stel’ar-ə) (ustekinumab) injection

Instructions for injecting STELARA® using a prefilled syringe.

Read this Instructions for Use before you start using STELARA®. Your doctor or nurse should show you how to prepare and give your injection of STELARA® the right way.

If you cannot give yourself the injection:

• ask your doctor or nurse to help you, or
• ask someone who has been trained by a doctor or nurse to give your injections.

Do not try to inject STELARA® yourself until you have been shown how to inject STELARA® by your doctor, nurse or health professional.

Important information:

• Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by your doctor.
  o If your dose is 45 mg, you will receive one 45 mg prefilled syringe.
  o If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg pre-filled syringes. If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself two injections, one right after the other.

• Check the expiration date on the prefilled syringe and carton. If the expiration date has passed, do not use it. If the expiration date has passed call your doctor or pharmacist, or call 1-800-JANSSEN (1-800-526-7736) for help.

• Make sure the syringe is not damaged.

• Check your prefilled syringe for any particles or discoloration. Your prefilled syringe should look clear and colorless to light yellow with few white particles.

• Do not use if it is frozen, discolored, cloudy or has large particles. Get a new prefilled syringe.

• Do not shake the prefilled syringe at any time. Shaking your prefilled syringe may damage your STELARA® medicine. If your prefilled syringe has been shaken, do not use it. Get a new prefilled syringe.

• To reduce the risk of accidental needle sticks, each prefilled syringe has a needle guard that is automatically activated to cover the needle after you have given your injection. Do not pull back on the plunger at any time.

Gather the supplies you will need to prepare and to give your injection. (See Figure A)

You will need:

• antiseptic wipes
• cotton balls or gauze pads
• your prescribed dose of STELARA® (See Figure B)
• FDA-cleared sharps disposal container. See “STEP 4: Dispose of syringe.”

Step 1: Prepare the injection.

• Choose a well lit, clean, flat work surface.
• Wash your hands well with soap and warm water.
• Hold the prefilled syringe with the covered needle pointing upward.

Step 2: Prepare your injection site.

• Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. (See Figure C)

• Do not give an injection in an area of the skin that is tender, bruised, red or hard.

• Clean the skin with an antiseptic wipe where you plan to give your injection.

• Do not touch this area again before giving the injection. Let your skin dry before injecting.

• Do not fan or blow on the clean area.

Step 3: Inject STELARA®.

• Remove the needle cover when you are ready to inject your STELARA®.

• Do not touch the plunger while removing the needle cover.

• Hold the body of the prefilled syringe with one hand, and pull the needle cover straight off. (see Figure D)

• Put the needle cover in the trash.

• You may also see a drop of liquid at the end of the needle. This is normal.

• Do not touch the needle or let it touch anything.

• Do not use the prefilled syringe if it is dropped without the needle cover in place. Call your doctor, nurse or health professional for instructions.

Figure A

Figure B

Figure C

*Areas in gray are recommended injection sites.

Figure D
• Hold the body of the prefilled syringe in one hand between the thumb and index fingers. *(See Figure E)*

![Figure E](image)

• **Do not** pull back on the plunger at any time.
• Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
• Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle. *(See Figure F)*

![Figure F](image)

• Inject all of the liquid by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. *(See Figure G)*

![Figure G](image)

• When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.

• Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. *(See Figure H)*

![Figure H](image)

• When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

**Step 4: Dispose of the syringe.**
• Put the syringe in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose syringes in your household trash.**
• If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  o made of heavy-duty plastic
  o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  o upright and stable during use
  o leak-resistant,
  o and properly labeled to warn of hazardous waste inside the container.
• When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or state laws about how to throw away syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.
• Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
• If you have any questions, talk to your doctor or pharmacist.

*Keep STELARA® and all medicines out of the reach of children.*

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