Stelara®
(ustekinumab)

A STEP-BY-STEP GUIDE
TO HELP YOUR PEDIATRIC PATIENTS GET STARTED ON STELARA®

The So Simple Trial offer **only** applies to the STELARA® 45-mg single-dose vial. For patients requiring a 45-mg or 90-mg single-dose prefilled syringe sample, please contact your sales representative.

STELARA® is also approved for children 6 and up with moderate to severe plaque psoriasis

INDICATION

STELARA® (ustekinumab) is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

SELECTED IMPORTANT SAFETY INFORMATION

STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, mycobacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, Posterior Reversible Encephalopathy Syndrome (PRES), and noninfectious pneumonia. STELARA® should not be given to patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatmentwith STELARA®. Live vaccines should not be givento patients receiving STELARA®. If PRES is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see related and other Important Safety Information on page 4.

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

START WITH STELARA®
SO SIMPLE TRIAL PROGRAM

The STELARA® So Simple Trial Program provides pediatric patients requiring the 45-mg single-dose vial their first dose of STELARA® so they may determine with their provider if it is right for them.

1. **FORM** for easy enrollment
2. **$0 COST** to patient
3. Shipment can be authorized within **3 BUSINESS DAYS** after prescription.*

This trial program is open to patients who have commercial insurance, government coverage, or no insurance coverage. However, there is no guarantee of continuous accessibility after the program ends.

*Shipment can be authorized within 3 business days of submitting a prescription, pending patient program opt-in and scheduling shipment.

SUBMIT A COMPLETED PRESCRIPTION ENROLLMENT FORM

Please see related Important Safety Information on page 4.

These programs are for medication only. Terms expire at the end of each program year and may change.

FOR COMMERCIALLY INSURED PATIENTS

STAY WITH STELARA®

SUBMIT A COMPLETED PRIOR AUTHORIZATION FORM

to the patient's insurance company

Click here for Prior Authorization information

INSURANCE COVERAGE APPROVED

JANSSEN CAREPATH SAVINGS PROGRAM

Eligible patients pay $5 per injection

with a $20,000 maximum program benefit per calendar year

See full program requirements at Stelara.JanssenCarePathSavings.com.

Use the **EXPRESS ENROLLMENT** site at JanssenCarePathPortal.com/express to enroll eligible patients in the Janssen CarePath Savings Program

COVERAGE DELAYED >5 BUSINESS DAYS OR DENIED

Janssen Link

Patients will receive STELARA® **at no cost** until they receive insurance coverage approval

See full program requirements at JanssenCarePath.com/HCP/Stelara/Insurance-Coverage/Janssen-Link.

Both programs are unavailable to individuals who use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration.

Stelara® (ustekinumab)

HELP GET YOUR PEDIATRIC PATIENTS STARTED

THE STELARA® SO SIMPLE TRIAL OFFER IS AVAILABLE ONLY FOR THE 45-MG SINGLE-DOSE VIAL

Enrollment starts with completing

1 FORM

OFFICE ROLE

To start therapy:

Submit the fully completed and signed Prescription Enrollment Form (PEF) to Janssen CarePath.

Advise your patient's caregiver to accept all phone calls from Wegmans Specialty Pharmacy.

To stay on therapy:

Submit completed Prior Authorization and any other documentation required by the insurance company to determine the patient's insurance coverage.

Please see related Important Safety Information on page 4.

IMPORTANT REMINDERS FOR CAREGIVERS TO ENROLL IN SO SIMPLE

FOR PATIENTS REQUIRING WEIGHT-BASED DOSING

Enrollment starts with your patients and their caregivers accepting

2 PHONE CALLS

CAREGIVER ROLE

Set an appointment for the child to receive the first injection of STELARA®.

Accept 2 important calls from Wegmans Specialty Pharmacy from 866-889-5660.

Call #1: Within 1 business day—to complete the So Simple Trial Program enrollment.

Call #2: Within 14-21 days after starting STELARA®—to confirm continuation of therapy and to learn about insurance coverage options.

Stelara® (ustekinumab)

IMPORTANT SAFETY INFORMATION

STELARA® (ustekinumab) is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients.

Infections

STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and *Listeria* meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Treatment with STELARA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of STELARA® in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with STELARA® and consider discontinuing STELARA® for serious or clinically significant infections until the infection resolves or is adequately treated.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, *Salmonella*, 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® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered (eg, tissue culture, stool culture) as dictatedby clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with STELARA®. Do not administer STELARA® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STELARA®. Closely monitor patients receiving STELARA® for signs and symptoms of active TB during and after treatment.

Malignancies

STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STELARA® in clinical studies. 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 reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STELARA®, especially those >60 years or those with a history of PUVA or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with STELARA®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA®.

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis and Crohn's disease.Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent withPRES a few days to several months after ustekinumab initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with STELARA® for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STELARA®.

Immunizations

Prior to initiating therapy with STELARA®, patients should receive all age-appropriate immunizations recommended by current guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment or within one year of initiating or discontinuing STELARA®. Exercise caution when administering live vaccines to household contacts of STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease.

Concomitant Therapies

The safety of STELARA® in combination with other biologic immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant methotrexate use did not appear to influence the safety or efficacy of STELARA®. In Crohn's disease and ulcerative colitis induction studies, concomitant use of 6-mercaptopurine, azathioprine, methotrexate, and corticosteroids did not appear to influence the overall safety or efficacy of STELARA®.

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of STELARA®. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and, in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue STELARA® and institute appropriate treatment.

Allergen Immunotherapy

STELARA® 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.

Most Common Adverse Reactions

The most common adverse reactions (≥3% and higher than that with placebo) in adults from psoriasis clinical studies for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. The safety profile in pediatricpatients with plaque psoriasis was similar to that of adults with plaque psoriasis. In psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® when compared with placebo (3% vs 1% for both). In Crohn's disease induction studies, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn's disease maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 for STELARA® 90 mg subcutaneous injection or placebo were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%) and sinusitis (3% vs 2%). In the ulcerative colitis induction study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 for STELARA® 90 mg subcutaneous injection or placebo included: nasopharyngitis (24% vs 20%), headache (10% vs 4%), abdominal pain (7% vs 3%), influenza (6% vs 5%), fever (5% vs 4%), diarrhea (4% vs 1%), sinusitis (4% vs 1%), fatigue (4% vs 2%), and nausea (3% vs 2%).

Please click to see the full Prescribing Information and Medication Guide for STELARA®. Provide the Medication Guide to your patients and encourage discussion.

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INDICATIONS

STELARA® (ustekinumab) is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

STELARA®, available as 45 mg and 90 mg, is a subcutaneous injection intended for use under the guidance and supervision of a physician with patients who will be closely monitored and have regular follow-up visits with a physician. In pediatric patients, it is recommended that STELARA® be administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject or a caregiver may inject STELARA® after proper training in subcutaneous injection technique. Patients should be instructed to follow the directions provided in the Medication Guide.

Stelara® (ustekinumab)

For more information about Janssen CarePath, talk with your Janssen Representative.

Janssen CarePath

Call a Janssen CarePath Care Coordinator at
877-CarePath (877-227-3728), Monday-Friday 8:00 AM to 8:00 PM ET

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