

Nurse Navigators from Janssen CarePath

Dedicated STELARA® Nurse Navigators Provide Support to Help Your Patients Start and Stay on Prescribed Therapy



Education on how STELARA® is administered for Crohn's disease and ulcerative colitis



Connecting you to a specialist for cost and insurance coverage support, and connecting eligible patients with Janssen CarePath Savings Program or other financial assistance options



IV infusion center details and appointment reminders when patients are getting started on STELARA®



Live and virtual injection training* at no cost, so patients feel more confident with self-injection



Nurse Navigators who keep you and your patients informed

A dedicated Nurse Navigator will contact your office with important updates about your patients' treatment journey. The Nurse Navigator will provide education to help your patients be more confident with their STELARA® treatment.

Indications

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis

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.

Please see Important Safety Information continued on next page.

*May not be available in all areas. Patients are asked to give two weeks' notice when requesting self-injection training.

Janssen
CarePath

 **Stelara®**
(ustekinumab)

Important Safety Information (Cont'd)

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 dictated by 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 with PRES 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®.

Please see Important Safety Information continued on next page.

Janssen
CarePath

 **Stelara**[®]
(ustekinumab)

Important Safety Information (Cont'd)

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 pediatric patients 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.

cp-124933v3

STELARA® dosing for Crohn's disease and ulcerative colitis

Induction Dose: A single intravenous infusion using a weight-based dosage regimen: 260 mg (weight 55 kg or less), 390 mg (weight more than 55 kg to 85 kg), or 520 mg (weight more than 85 kg).

Maintenance Dose: A subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter. STELARA® is intended for use under the guidance and supervision of a physician with patients who will be closely monitored and have regular follow-up.

Nurse Navigators from Janssen CarePath

Connecting Your STELARA® Patients With a Dedicated Nurse Navigator Is Simple



Get your patients enrolled

Access the enrollment form at Nurse4STELARA.com, then have your patients complete it and follow the instructions.



Submit the completed form

There are multiple ways to enroll:

 **E-mail to:**
mynurse@janssennurse.com

 **Fax to:**
800-870-6237

 **Mail to:**
Nurse Navigators from
Janssen CarePath
500 Atrium Drive, 3rd Floor
Somerset, NJ 08873

 **Enroll online at:**
www.Nurse4Stelara.com



A dedicated Nurse Navigator will contact your patient

After completing enrollment, your patients will receive a call from a Nurse Navigator within 1 business day. The caller ID will display "Nurse Navigator."

Dedicated Nurse Navigators establish a one-on-one relationship with your patients and educate them throughout their treatment journey, while keeping you informed

To learn more about Nurse Navigators from Janssen CarePath, call 877-CarePath (877-227-3728) Monday–Friday | 8 AM–8 PM ET or visit STELARAHCP.com

The nurse program is limited to education for patients about their Janssen therapy, its administration and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

Please see Important Safety Information throughout. Please click to see the full [Prescribing Information](#) and [Medication Guide](#) for STELARA®. Provide the Medication Guide to your patients and encourage discussion.

Janssen
CarePath

 **Stelara®**
(ustekinumab)