Stelara® (ustekinumab)

UNIQUELY DESIGNED DOSING IN CD AND UC

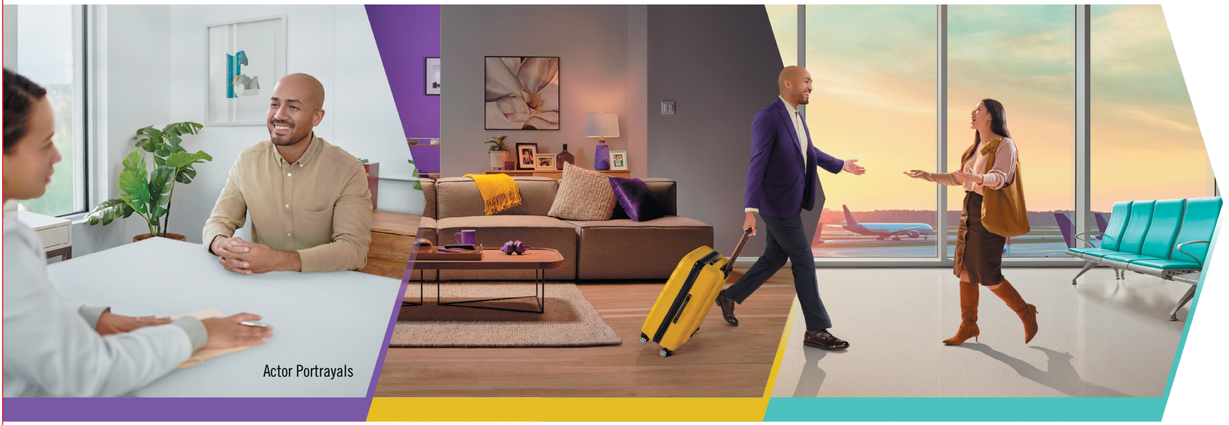
Only STELARA® offers one IV infusion followed by a q8w subQ maintenance regimen

For adults with moderately to severely active Crohn's disease (CD) or ulcerative colitis (UC).

A GUIDE TO DOSING AND ADMINISTRATION

IV=intravenous; q8w=every 8 weeks; subQ=subcutaneous.

START WITH STELARA® FOR LASTING REMISSION*[1]



*In both the CD and UC studies, many patients achieved clinical remission at 1 year with STELARA®.

Data for CD[1]:

Clinical Response† at Week 6 (Predominantly TNF Blocker-naïve‡) (Primary Endpoint):
- STELARA®: 56% (n=116/209); Placebo: 29% (n=60/209); *P*<0.001

Clinical Response† at Week 6 (TNF Blocker-failure) (Primary Endpoint):
- STELARA®: 34% (n=84/249); Placebo: 21% (n=53/247); *P*<0.01

Clinical Remission§ at 1 Year (Overall Population) (Primary Endpoint):
- STELARA®: 53% (n=68/128); Placebo: 36% (n=47/131); *P*<0.01

Data for UC[1]:

Clinical Response† at Week 8 (Overall Population) (Major Secondary Endpoint):
- STELARA®: 58% (n=186/322); Placebo: 31% (n=99/319); *P*<0.001

Clinical Remission§ at Week 8 (Overall Population) (Primary Endpoint):
- STELARA®: 19% (n=62/322); Placebo: 7% (n=22/319); *P*<0.001

Clinical Remission§ at 1 Year (Overall Population) (Primary Endpoint):
- STELARA®: 45% (n=79/176); Placebo: 26% (n=46/175); *P*≤0.001

For additional information, including the study design, please visit www.stelarahcp.com.

Stelara® (ustekinumab)

TNF=tumor necrosis factor.

†In CD, clinical response was defined as reduction in Crohn's Disease Activity Index (CDAI) score of ≥100 points or CDAI score of <150. In UC, clinical response was defined as a decrease from baseline in the modified Mayo score by ≥30% and ≥2 points, with either a decrease from baseline in the rectal bleeding subscore of ≥1 or a rectal bleeding subscore of 0 or 1.

‡69% of patients were TNF blocker-naïve. Remaining population were patients previously exposed to, but who did not fail, treatment with TNF blockers. All patients in the study failed or were intolerant to conventional treatment (eg, azathioprine, 6-mercaptopurine, methotrexate, or corticosteroids).

§In CD, clinical remission was defined as a CDAI score of <150. In UC, clinical remission was defined as Mayo stool frequency subscore of 0 or 1, Mayo rectal bleeding subscore of 0, and Mayo endoscopy subscore of 0 or 1 (modified so that 1 does not include friability).

Reference: 1. STELARA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

RELEVANT DOSING INFORMATION

UNIQUELY DESIGNED IV AND SUBQ DOSING IN CD + UC 4

FEWEST DOSES AMONG SELECT CD + UC BIOLOGICS IN THE FIRST YEAR 5

OPTION OF AT-HOME OR IN-OFFICE MAINTENANCE DOSING 6

INSTRUCTIONS FOR IV ADMINISTRATION 7

INSTRUCTIONS FOR SUBQ ADMINISTRATION 8

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 treatment with STELARA®. Live vaccines should not be given to patients receiving STELARA®. If PRES is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

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STELARA® UNIQUELY DESIGNED DOSING IN CD + UC

INDUCTION

1 SINGLE IV DOSE

Administered over at least 1 hour

Body weight of patient at time of dosing	Dose	Number of 130 mg/26 mL (5 mg/mL) STELARA® vials
55 kg or less	260 mg	2
More than 55 kg to 85 kg	390 mg	3
More than 85 kg	520 mg	4

MAINTENANCE

1 90mg INJECTION EVERY 8 WEEKS

ONLY 6 SUBQ MAINTENANCE DOSES
During Year 1

Please refer to the Dosage and Administration section of the full Prescribing Information for complete information on how to prepare and administer STELARA®. 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. Patients may self-inject with STELARA® after physician approval and proper training. Patients should be instructed to follow the direction provided in the Medication Guide.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

STELARA® OFFERS THE FEWEST DOSES AMONG SELECT CD + UC BIOLOGICS IN THE FIRST YEAR

			TOTAL	
STELARA®*	1 Induction	6 Maintenance	7	Single IV weight-based induction dose administered over at least 1 hour; 6 subQ injection maintenance doses of 90 mg (1 every 8 weeks after induction dose).
Entyvio®† (vedolizumab)	3 Induction	5 Maintenance	8	300 mg IV infusion, administered over a period of about 30 minutes, at 0, 2, and 6 weeks, and then every 8 weeks thereafter.
Humira®‡ (adalimumab)	2 Induction	25 Maintenance	27	Three starter injections of 80 mg in 2 doses (on Day 1 and Day 15); 25 subQ injection maintenance doses of 40 mg (1 every other week thereafter).

KEY — IV Infusion | SubQ injection prefilled syringe | SubQ injection pen

This presentation is not intended to compare the relative safety or efficacy of these treatments. Please refer to each product's full Prescribing Information.

PRODUCT INDICATIONS IN CD + UC

Entyvio® (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD and moderately to severely active UC.
Humira® (adalimumab) is indicated in adults for the treatment of moderately to severely active CD and moderately to severely active UC.
• Limitations of use for UC: The effectiveness of Humira® has not been established in patients who have lost response to or were intolerant to TNF blockers.

TNF=tumor necrosis factor.
*Induction dose: A single IV infusion using a weight-based dosage regimen: STELARA® 260 mg (weight ≤55 kg), STELARA® 390 mg (weight >55 kg to 85 kg), STELARA® 520 mg (weight >85 kg). Maintenance dose: A subQ 90 mg dose administered every 8 weeks after the induction dose.
†Based on 300 mg administered by IV.
‡The recommended dosing for Humira® is 160 mg initially on Day 1 (given in 1 day or split over 2 consecutive days), followed by 80 mg 2 weeks later (Day 15). Two weeks later (Day 29), begin a maintenance dose of 40 mg every other week. Indicated trademarks are registered trademarks of their respective owners.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

STELARA® OFFERS THE OPTION OF AT-HOME OR IN-OFFICE MAINTENANCE DOSING

Provide the power of choice: in-office or at-home administration after physician approval and proper training

PROVIDER + PATIENT

ADMINISTERED BY HCP

IN OFFICE, HOPD, etc.

Two 45 mg/0.5 mL vials, one right after the other

PATIENT

ADMINISTERED BY PATIENT

AT HOME

90 mg/mL solution in a single-dose prefilled syringe

HCP=healthcare provider; HOPD=hospital outpatient department.

Please see Dosage and Administration section of the full Prescribing Information for complete information on storage and how to prepare and administer STELARA®.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

INSTRUCTIONS FOR IV ADMINISTRATION

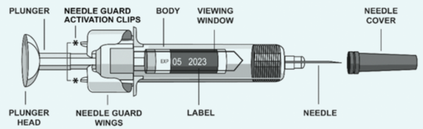
STELARA® solution for intravenous infusion must be diluted, prepared and infused by a healthcare professional using aseptic technique

1. Calculate the dose and the number of STELARA® vials needed based on patient weight. (See Table 3 in Prescribing Information.) Each 26 mL vial of STELARA® contains 130 mg of ustekinumab.
2. Withdraw, and then discard a volume of the 0.9% Sodium Chloride Injection, USP from the 250 mL infusion bag equal to the volume of STELARA® to be added (discard 26 mL sodium chloride for each vial of STELARA® needed, for 2 vials- discard 52 mL, for 3 vials- discard 78 mL, 4 vials- discard 104 mL). Alternatively, a 250 mL infusion bag containing 0.45% Sodium Chloride Injection, USP may be used.
3. Withdraw 26 mL of STELARA® from each vial needed and add it to the 250 mL infusion bag. The final volume in the infusion bag should be 250 mL. Gently mix.
4. Visually inspect the diluted solution before infusion. Do not use if visibly opaque particles, discoloration or foreign particles are observed.
5. Infuse the diluted solution over a period of at least one hour. Once diluted, the infusion should be completely administered within eight hours of the dilution in the infusion bag.
6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer).
7. Do not infuse STELARA® concomitantly in the same intravenous line with other agents.
8. STELARA® does not contain preservatives. Each vial is for single use only. Discard any remaining solution. Dispose any unused medicinal product in accordance with local requirements.

Please see Dosage and Administration section of the full Prescribing Information for complete information on storage and how to prepare and administer STELARA®.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

INSTRUCTIONS FOR SUBQ ADMINISTRATION



- After proper training, a patient may self-inject subcutaneously with STELARA® if a physician determines that it is appropriate. Patients should follow 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). The needle cover should not be handled by persons sensitive to latex.
- **Do not shake STELARA®.**
- It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of the abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated.
- Prior to administration, visually inspect STELARA® for particulate matter and discoloration. STELARA® is a colorless to light yellow solution and may contain a few small translucent or white particles. Do not use STELARA® if it is discolored or cloudy, or if other particulate matter is present. STELARA® does not contain preservatives; therefore, discard any unused product remaining in the syringe.

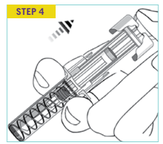
Instructions for administration of STELARA® prefilled syringes equipped with needle safety guard

Refer to the diagram to the left 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.

1. 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.**
2. Inject STELARA® subcutaneously as recommended.
3. 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.**

4. 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.



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

Please review the Instructions for Use on how to prepare and inject STELARA® and discuss with your patients.

Please see Dosage and Administration section of the full Prescribing Information for complete information on storage and how to prepare and administer STELARA®.

Please see related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

PRESCRIBING STELARA®?

Nurse Navigators provide support to help your patients start and stay on STELARA®

SCAN TO LEARN MORE

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 related and other Important Safety Information on pages 9-11 and full Prescribing Information in pocket.

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,

IMPORTANT SAFETY INFORMATION (cont'd)

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

cp-124933v5

Stelara®
(ustekinumab)

Janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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