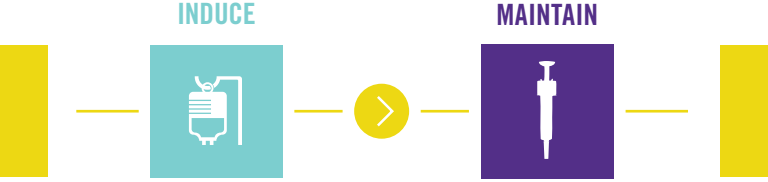
For your adult patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis

STELARA® DOSING GUIDE



With a Single IV Induction[1]

With SubQ Maintenance Every 8 Weeks[1]

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.

Please see additional Important Safety Information continued on next page.

Stelara® (ustekinumab)

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

DOSING—UNIQUELY DESIGNED FOR CROHN'S DISEASE AND ULCERATIVE COLITIS

STELARA® dosing is uniquely designed for your adult patients with moderately to severely active Crohn's disease or ulcerative colitis by combining a single intravenous (IV) induction with subcutaneous (subQ) maintenance

A Single IV Induction[1]

Single IV induction dose administered over at least 1 hour

Body weight* of patient at the 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

*Approximately 2.2 pounds per kilogram.

Important Safety Information (cont'd)

Infections (cont'd)

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 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.

SubQ Maintenance[1]

90-mg dose every 8 weeks after induction dose

6 subQ maintenance doses during Year 1

- Please refer to the Dosage and Administration section of the 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

For optimal outcome, STELARA® should be dosed and administered as described in the Prescribing Information

Important Safety Information (cont'd)

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.

Please see additional Important Safety Information continued on next page.

Stelara® (ustekinumab)

NUMBER OF DOSES AMONG SELECT BIOLOGICS FOR CD AND UD

Total doses in the first 52 weeks for adult patients

STELARA®
(ustekinumab)[1*]

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 IV induction dose).

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.

Entyvio®
(vedolizumab)[2†]

8

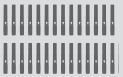
300-mg IV infusion, administered over a period of about 30 minutes, at 0, 2, and 6 weeks, and then every 8 weeks thereafter.

Entyvio® (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

Entyvio® is indicated in adults for the treatment of moderately to severely active CD.

Humira®
(adalimumab)[3‡]

28



Three starter injections of 80 mg in 2 doses; 25 subQ injection maintenance doses of 40 mg (1 every other week thereafter).

Humira® is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Humira® is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Humira® is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine. The effectiveness of Humira® has not been established in patients who have lost response to or were intolerant to TNF blockers.

This is not intended to compare the relative safety or efficacy of these treatments. Please refer to each product's Prescribing Information for recommended dosing and administration.

CD=Crohn's disease; IV=intravenous; subQ=subcutaneous; UC=ulcerative colitis.

* Induction dose: A single IV infusion using a weight-based dosage regimen: STELARA® 260 mg (weight 55 kg or less), 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.

References: 1. STELARA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Entyvio® [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc. **3.** Humira® [prescribing information]. North Chicago, IL: AbbVie Inc.

Important Safety Information (cont'd)

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®.

Immunization

Prior to initiating therapy with STELARA®, patients should receive all age-appropriate immunizations recommended by current guidelines.

Important Safety Information (cont'd)

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.

Please see additional Important Safety Information continued on next page.

Important Safety Information (cont'd)

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.

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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.

Stelara® (ustekinumab)