Initiate treatment with STELARA® with a single intravenous (IV) infusion using the weight-based dosage regimen shown in the table below.

<table>
<thead>
<tr>
<th>Body Weight* of Patient at the Time of Dosing</th>
<th>Dose</th>
<th>Number of 130 mg/26 mL (5 mg/mL) STELARA® Vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 kg or less</td>
<td>260 mg</td>
<td>2</td>
</tr>
<tr>
<td>more than 55 kg to 85 kg</td>
<td>390 mg</td>
<td>3</td>
</tr>
<tr>
<td>more than 85 kg</td>
<td>520 mg</td>
<td>4</td>
</tr>
</tbody>
</table>

*Approximately 2.2 pounds per kilogram.

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

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

If necessary, the diluted infusion solution may be stored for up to 4 hours at room temperature up to 25°C (77°F). Do not freeze. Discard any unused portion of the infusion solution.

**Indication**

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:

- failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
- failed or were intolerant to treatment with one or more TNF blockers.

**Selected Important Safety Information**

STELARA® is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS), and noninfectious pneumonia.

STELARA® should not be given to patients who have had clinically significant hypersensitivity to ustekinumab (or excipients) or 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 RPLS is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see related and other Important Safety Information.
**SubQ MAINTENANCE DOSING**

STEMLARA® treatment continues with a subcutaneous (subQ) 90-mg dose 8 weeks after the initial IV dose, then every 8 weeks thereafter.

- After proper training in subQ injection technique, a patient may self-inject with STEMLARA® if a physician determines that it is appropriate. Patients should be instructed to follow the directions provided in the Medication Guide.
- 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.
- 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.
- STEMLARA® is intended for use under the guidance and supervision of a physician. STEMLARA® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- Prior to administration, visually inspect STEMLARA® for particulate matter and discoloration. STEMLARA® is clear, colorless to light yellow, and may contain a few small translucent or white particles. Do not use STEMLARA® if it is discolored or cloudy, or if other particulate matter is present. STEMLARA® does not contain preservatives; therefore, discard any unused product remaining in the syringe.

**Indication**

STEMLARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:
- failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
- failed or were intolerant to treatment with one or more TNF blockers.

**Selected Important Safety Information**

STEMLARA® is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STEMLARA®-treated patients, including bacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS), and noninfectious pneumonia.

STEMLARA® should not be given to patients who have had clinically significant hypersensitivity to ustekinumab (or excipients) or patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with STEMLARA®. Live vaccines should not be given to patients receiving STEMLARA®. If RPLS is suspected or if noninfectious pneumonia is confirmed, discontinue STEMLARA®.

Please see related and other Important Safety Information.
**Important Safety Information**

**Infections**

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In patients with psoriatic arthritis, serious infections included cholecystitis. In patients with Crohn’s disease, serious or other clinically significant infections included anal abscess, gastroenteritis, ophthalmic herpes, pneumonia, and *Listeria meningitis*.

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, e.g., 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**

STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. 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®.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS)**

One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed in clinical studies of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical studies of Crohn’s disease. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®. RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.
**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 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 MTX use did not appear to influence the safety or efficacy of STELARA®. In Crohn’s disease 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 adolescents with plaque psoriasis through Week 60 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 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%).

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

**For Crohn’s Disease:**
STELARA® for intravenous infusion is available as a 130 mg/26 mL (5 mg/mL) single-dose vial. It must be diluted, prepared, and infused by a healthcare professional for Crohn’s disease.

STELARA®, available as 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. 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.