

# Specialty Distributors for STELARA™

STELARA™ is available from the specialty distributors listed below

<b>Besse Medical—A Division of the AmerisourceBergen Specialty Group</b> (Dermatology)	(877) 736-4223 (888) 772-8578
<b>Cardinal Health Specialty Pharmaceutical Distribution</b>	(866) 677-4844
<b>CuraScript Inc. Specialty Distribution</b>	(800) 942-5999
<b>Florida Infusion/NationsDrug</b>	(800) 624-0152
<b>McKesson Specialty Care Solutions</b>	(888) 625-7732
<b>Oncology Supply—A Division of the AmerisourceBergen Specialty Group</b>	(800) 633-7555
<b>Metro Medical Supply, Inc.</b>	(800) 768-2002

Please see Indication and Important Safety Information on reverse side and accompanying Full Prescribing Information and Medication Guide for STELARA™.



## INDICATION FOR STELARA™ (ustekinumab)

STELARA™ is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

## IMPORTANT SAFETY INFORMATION

### Infections

STELARA™ (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were reported. Infections requiring hospitalization included cellulitis, diverticulitis, osteomyelitis, gastroenteritis, pneumonia, and urinary tract infections. STELARA™ should not be given to patients with a clinically important active infection and should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering use of STELARA™ in patients with a chronic infection or a history of recurrent infection.

### Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacterium, *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™ will be susceptible to these types of infections. Consider appropriate diagnostic testing as dictated by clinical circumstances.

### Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with STELARA™. STELARA™ should not be given to patients with active TB. Initiate treatment of latent TB before administering STELARA™. Patients should be monitored closely for signs and symptoms of active TB during and after treatment with STELARA™.

### 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.

### Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of RPLS has been reported in a STELARA™-treated patient. If RPLS is suspected, discontinue STELARA™ and administer appropriate treatment.

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 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 has not been evaluated. Ultraviolet-induced skin cancers developed earlier and more frequently in mice genetically manipulated to be deficient in both IL-12 and IL-23 or IL-12 alone. The relevance of these findings in mouse models for malignancy risk in humans is unknown.

### Most Common Adverse Reactions

The most common adverse reactions ( $\geq 3\%$  and higher than that with placebo) in clinical trials 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.

**Please see accompanying Full Prescribing Information and Medication Guide for STELARA™.**

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