STELARA® (ustekinumab) is a human monoclonal antibody that is indicated for the following:
- treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- treatment of adult patients with active psoriatic arthritis (alone or in combination with methotrexate).

STELARA® targets interleukin-12 (IL-12) and interleukin-23 (IL-23). Based on data from rodent models and humans genetically deficient for components of IL-12 and IL-23 pathways, there is a theoretical concern that blockade of IL-12 and IL-23 may increase the risk for serious infections, including mycobacterial and recurrent salmonella infections.

If you are consulted to see a patient that develops a serious infection while being treated with STELARA®, it is important that you report the case even if you do not think there is a causal relationship.

The information that you, as a gastroenterologist, can provide may inform therapy and monitoring decisions for psoriasis patients.

**Reporting is easy and maintains patient confidentiality.** Your patient’s name or contact information is not needed. HIPAA does not apply to this adverse event reporting.

You can report your cases to the STELARA® manufacturer or directly to FDA.
- Janssen Biotech, Inc. at 1-800-526-7736
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm
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/s/

BADRUL A CHOWDHURY
09/20/2013