Janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

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Stelara™ (ustekinumab): Important safety information for potential risks of serious infections, malignancies, RPLS and serious skin conditions

Dear Healthcare Professional:

Janssen Cilag would like to inform you of important safety information for STELARA™ (ustekinumab), a new human monoclonal antibody which has been approved by Saudi Food and Drug Authority for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. STELARA™ targets interleukin-12 (IL-1 2) and interleukin-23 (IL-23).

The Saudi Food and Drug Authority has requested that physicians be advised of the potential risks of serious infections and malignancy, reversible posterior leukoencephalopathy syndrome (RPLS) and serious skin conditions.

The following information is important for healthcare professionals and patients treated with STELARA™:

Infections

- STELARA™ may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were observed in patients receiving STELARA™. 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 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™ will be susceptible to these types of infections. Appropriate diagnostic testing should be considered as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

- Evaluate patients for TB infection prior to initiating treatment with STELARA™. Do not administer STELARA™ to patients with active TB. Initiate treatment of latent TB before administering STELARA™

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- Consider anti-tuberculosis therapy prior to initiation of STELARA™ in patients with a past history
- Of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed.
- Patients receiving STELARA™ should be monitored closely for signs and symptoms of active TB during and after treatment.

Malignancies

- STELARA™ (ustekinumab) is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among subjects 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 subject in clinical studies.
- RPLS is a neurological disorder, which is not caused by demyelination or a known infectious agent. RPLS can present with headache, seizures, confusion and visual disturbances. It has been associated with preeclampsia, eclampsia, acute hypertension, cytotoxic agents and immunosuppressive therapy.
- If RPLS is suspected, discontinue STELARA™ and administer appropriate treatment.

Serious Skin Conditions

- In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment. Exfoliative dermatitis is an erythematous, scaly dermatitis.
- Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease.
- As part of the monitoring of the patient's psoriasis, physicians should be alert for symptoms of erythrodermic psoriasis or exfoliative dermatitis. If these symptoms occur, appropriate therapy should be instituted. STELARA should be discontinued if a drug reaction is suspected

Further information on the safety concerns and recommendations:

Ustekinumab is a fully human IgGlK IgG1k monoclonal antibody to IL-12/23, for the treatment of moderate to severe plaque psoriasis in adult patients.

The theoretical risk of serious infections (including mycobacteria and salmonella infections), malignancies and RPLS has been monitored for over 5 years of post-approval use. The safety surveillance methods have not identified any safety signals with respect to these risks. In case of exfoliative dermatitis while some cases occurred within a few days of the patient receiving ustekinumab, the role of underlying psoriasis in these patients could not be ruled out completely. Patients with plaque psoriasis may develop erythrodermic psoriasis as part of the natural course of their disease.

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The information in this letter has been approved by the Saudi Food and Drug Authority.

Reporting patient adverse events

It is important that you report all serious adverse events that occur in patients using STELARA™. If you have a patient who develops a serious infection, serious skin condition or RPLS while being treated with STELARA™, or if you have a patient with cancer at any time after receiving STELARA™ therapy, it is important that you report the case even if you do not think there is a causal relationship.

Call for reporting

Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.

SFDA (National pharmacovigilance and drug safety department)
Email to: npc.drug@sfda.sa
Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa/

Or
You can contact company scientific office at:
Email to: GCC-PV2@its.jnj.com
Fax: +966-11-2153190

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