DHPC agreed by PRAC on 9 October 2014

21st November 2014

Direct Healthcare Professional Communication
Stelara® (Ustekinumab) solution for injection in pre-filled syringe
Risk of exfoliative dermatitis and skin exfoliation

Dear Healthcare professional,

Janssen, in cooperation with the European Medicines Agency (EMA) and the Health Products Regulatory Authority (HPRA), would like to inform you of the following:

- Cases of exfoliative dermatitis have been reported, although rarely, in psoriasis patients receiving ustekinumab. Skin exfoliation without other symptoms of exfoliative dermatitis has also been reported.
- Be alert for symptoms of exfoliative dermatitis in patients receiving ustekinumab. The symptoms of exfoliative dermatitis may be indistinguishable from erythrodermic psoriasis. Patients with plaque psoriasis may develop erythrodermic psoriasis as part of the natural course of their disease.
- If a patient develops these symptoms, start appropriate therapy promptly. Stop ustekinumab treatment if you suspect these symptoms to have been caused by a drug reaction.
- Tell patients receiving ustekinumab to watch out for symptoms of erythrodermic psoriasis or exfoliative dermatitis (e.g. an increase in redness and shedding of skin over a larger area of the body). Advise them to tell their doctor if they notice any of these symptoms.

Further information on the safety concern and the recommendations
Ustekinumab is a fully human IgG1κ monoclonal antibody to IL-12/23, for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in adult patients.

There have been rare (≥1/10,000 to<1/1,000) reports of exfoliative dermatitis in psoriasis patients receiving ustekinumab. In some cases, exfoliative dermatitis occurred within a few days of the patient receiving ustekinumab, suggesting a possible relationship with ustekinumab. Some cases were severe and required hospitalisation. There have also been uncommon (≥1/1,000 to<1/100) reports of skin exfoliation occurring without other symptoms of exfoliative dermatitis.

The following information has been added to the Stelara Summary of Product Characteristics (SmPC):

4.4 Special warnings and precautions for use

Serious skin conditions
In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment (see section 4.8). 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.

4.8 Undesirable effects

Exfoliative dermatitis has been added in Table 1 as rare (≥1/10,000 to<1/1,000) adverse drug reaction of Stelara and skin exfoliation has been added as uncommon (≥1/1,000 to<1/100) adverse drug reaction of Stelara.

The package leaflet has been updated accordingly.

Reporting adverse drug reactions
Reporting suspected adverse reactions after authorisation of a medicinal product is important. It allows continued monitoring of the balance of benefits and the risks of the medicinal product.

Please continue to report any suspected adverse drug reactions to the Health Products Regulatory Authority, online at www.hpra.ie, by email at medsafety@hpra.ie, telephone 353 1 6764971, fax: 353 1 6767836 or by post at 'FREEPOST', HPRA, Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Suspected adverse reactions should also be reported to Janssen on tel: 0044 1494 567 447, fax: 0044 1494 567799 or by email at dsafety@its.jnj.com.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point
If you have further questions, please contact the Janssen Medical Information team on 1800 709122 or medinfo@janssen-cilag.co.uk.

Yours faithfully,

Mikhail Nikonorov

Head of Medical Affairs
Janssen Ireland