DHPC agreed by PRAC on 9 October 2014

21st November 2014

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 Medicines and Healthcare products Regulatory Agency (MHRA), 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.

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4.8 Undesirable effects

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

The package leaflet has been updated accordingly.

Reporting adverse drug reactions
Please continue to report any suspected adverse drug reactions, including accidental exposure, to the MHRA through the Yellow Card Scheme: www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: FREEPOST YELLOW CARD
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by electronic download through the Yellow Card section of the MHRA website

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

Suspected adverse reactions should also be reported to Janssen on tel: 0800-3893640, fax: 0800-3893644 or by email at dsafety@its.jnj.com.

Company contact point
If you have further questions, please contact the Janssen Medical Information team on 0800-7318450 or medinfo@janssen-cilag.co.uk or the Janssen Customer Service centre on 0800-7315550.

Yours faithfully,

PMF Barnes MBBS FFPM

Medical Director, Janssen