

**Health Canada Endorsed Important Safety Information on
STELARA® (ustekinumab)**



November 21, 2014

Dear Healthcare Professional:

**Subject: Risk of exfoliative dermatitis and erythrodermic psoriasis with
STELARA® (ustekinumab)**

Janssen Inc., in consultation with Health Canada, would like to inform you of important new safety information regarding the risk of exfoliative dermatitis and erythrodermic psoriasis associated with the use of STELARA®.

STELARA® is approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in adult patients.

- Cases of exfoliative dermatitis and erythrodermic psoriasis have been reported rarely in psoriasis patients receiving STELARA®. These skin conditions can occur within a few days of the patient receiving STELARA®. They can be severe and lead to hospitalization.
- The Product Monograph for STELARA® will be updated to include the adverse events of exfoliative dermatitis and erythrodermic psoriasis. Please refer to the STELARA® Product Monograph for full prescribing information.
- The symptoms of exfoliative dermatitis may be indistinguishable from erythrodermic psoriasis. Advise your patients to watch for and report these symptoms. In case of occurrence of these symptoms, appropriate therapy should be initiated. Treatment with STELARA® should be discontinued if a drug reaction is suspected.

There have been rare ($\geq 1/10,000$ to $< 1/1,000$) reports of exfoliative dermatitis and erythrodermic psoriasis in psoriasis patients receiving ustekinumab. 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.

Physicians should be alert for symptoms of exfoliative dermatitis. These can appear as redness and shedding of the skin over almost the entire area of the body, which may be itchy and/ or painful.

A copy of this letter and the Canadian Product Monograph can be accessed at the Health Canada web site and at www.janssen.ca

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious exfoliative dermatitis or erythrodermic psoriasis or other serious or unexpected adverse reactions in patients receiving STELARA® should be reported to Janssen Inc. or Health Canada.

Drug Safety Department
Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Or call toll-free 1-866-825-7122
Or email to dssc@joica.jnj.com
Or fax to 1-866-787-5865

To correct your mailing address, fax number or transmission difficulties please, contact Janssen Inc. email info@ptm-health.com or fax 1-888-780-4268.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpssc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Should you have any questions or require additional information, please contact Janssen Inc. Medical Information Department at 1-800-567-3331 or 1-800-387-8781 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time (EST).

Sincerely,



Cathy Lau, Ph.D.
Vice President
Regulatory Affairs and Quality Management

All trademarks used under license.