

**Public Communication -
Health Canada Endorsed Important Safety Information on
STELARA[®] (ustekinumab)**



November 21, 2014

Subject: Risk of rare serious skin conditions in patients treated with STELARA[®] (ustekinumab)

Janssen Inc., in consultation with Health Canada, would like to inform you about important new safety information regarding the risk of rare serious skin conditions (exfoliative dermatitis and erythrodermic psoriasis) which have been reported in patients treated with STELARA[®].

STELARA[®] is a medication used to treat moderate to severe plaque psoriasis and/ or psoriatic arthritis.

- Cases of serious skin conditions, exfoliative dermatitis and erythrodermic psoriasis have been reported rarely in persons who were being treated with STELARA[®].
- Exfoliative dermatitis and erythrodermic psoriasis can appear as redness and shedding of the skin over almost the entire area of the body. This rash may be itchy and/ or painful and may occur, within a few days after receiving STELARA[®].
- If you experience the symptoms mentioned above, speak to your doctor immediately. If a severe skin reaction is confirmed by your doctor, treatment with STELARA[®] may need to be stopped.

Janssen Inc. is working with Health Canada to update the safety information for STELARA[®] and has sent a letter to health care professionals to inform them of this new important safety information. A copy of that letter is available on the Health Canada web site. This information is also available www.janssen.ca.

If you have any questions regarding your treatment with STELARA[®], please contact your doctor.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious skin reactions or other serious or unexpected side effects 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 dsscan@joica.jnj.com

Or fax to 1-866-787-5865

You can report any suspected side effect 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_dpdc.public@hc-sc.gc.ca

Telephone: 613-954-6522

Fax: 613-952-7738