Important Safety Information on ARANESP – Risk of Severe Skin Reactions: Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis

2017/05/05

Audience

Healthcare professionals including oncologists, nephrologists, hematologists, nurses, dermatologists, pharmacists, emergency room staff, and cancer clinic staff.

Key messages

- **Severe and life-threatening skin reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in patients treated with ARANESP (darbepoetin alfa).**
- **Healthcare professionals are advised to:**
  - **discontinue ARANESP therapy immediately if a severe skin reaction occurs or SJS/TEN is suspected.**
  - **permanently discontinue ARANESP if SJS/TEN is confirmed.**
- **Health Canada is currently working with the manufacturer to include this safety information in the Canadian Product Monograph.**

What is the issue?
Severe blistering, mucosal ulceration, and exfoliation cutaneous reactions, including life-threatening SJS and TEN have been reported in patients treated with ARANESP in the post-marketing setting.

Products affected
ARANESP (darbepoetin alfa) products for subcutaneous and intravenous use.

Background information
ARANESP, an erythropoiesis-stimulating agent, is indicated for the treatment of anemia associated with chronic kidney disease (CKD) or anemia in cancer patients receiving chemotherapy.

As of October 31, 2016, cumulative exposure to ARANESP was estimated to be over 6 million patient-years in the post-marketing setting. The potential risk of SJS/TEN with ARANESP use was evaluated using the global safety databases. As of April 5, 2017, 11 cases of SJS and 4 cases of TEN have been reported internationally in patients treated with ARANESP. To date no Canadian cases of SJS/TEN related to ARANESP treatment have been identified.

Information for consumers
ARANESP is a prescription medicine used to treat anemia associated with chronic kidney disease (kidney failure) or anemia associated with chemotherapy administration in cancer patients.

In some patients, ARANESP has been associated with severe skin reactions, including life-threatening reactions called Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). SJS/TEN are serious life-threatening conditions that often begin with flu-like symptoms including fever, tiredness, muscle and joint pain which are followed by a widespread rash with reddening and blistering of the skin and moist lining of the mouth, eyes, nose, throat, or genital area. This often leads to peeling and shedding of the affected skin which looks like a severe burn. Patients should discuss any skin reaction with their doctor, and seek immediate medical attention if they experience any of the SJS/TEN symptoms.

Patients should inform their healthcare professional if they are experiencing a side effect related to ARANESP treatment.

Information for healthcare professionals
Healthcare professionals are reminded to:

- discontinue ARANESP therapy immediately if a severe skin reaction occurs or SJS/TEN is suspected.
- permanently discontinue ARANESP if SJS/TEN is confirmed.

Action taken by Health Canada
Health Canada is currently working with the manufacturer to include this safety information in the Canadian Product Monograph.

Health Canada is communicating this important safety information update to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site (www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php).

This communication update will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of severe skin reactions, suspected SJS or TEN or other serious or unexpected side effects in patients receiving ARANESP should be reported to Amgen Canada Inc. or Health Canada.

Amgen Canada Inc.
6775 Financial Drive, Suite 100
Mississauga, Ontario L5N 0A4

Safety Tel: 1-866-512-6436 or Fax: 1-888-264-3655
Safety e-mail: safetycanada@amgen.com

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) 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_dpsc@hc-sc.gc.ca
Telephone: 613-964-6522
Fax: 613-952-7738

Original signed by

Clive Ward-Able, MD
Executive Medical Director
AMGEN Canada Inc.