

Drug Injury Watch: Health Canada Increases Warnings About Aranesp Skin Adverse Reactions

(Posted by Tom Lamb at www.DrugInjuryWatch.com on May 18, 2017)

On May 5, 2017 the Canadian drug regulatory agency issued this Dear Healthcare Professional Letter: "ARANESP - Risk of Severe Skin Reactions: Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis".

From this recent Health Canada Aranesp alert we get this updated drug safety information:

- 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.
- 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.

This so-called "Dear Doctor" letter about Aranesp also informed that Health Canada is currently working with the manufacturer, Amgen Canada Inc., to include this safety information in the Canadian Product Monograph for Aranesp.

Aranesp (darbepoetin alfa) products for subcutaneous and intravenous use are approved by the FDA for two indications: (1) anemia due to chronic kidney disease; and, (2) anemia due to chemotherapy in patients with cancer.

We will be watching to see whether the FDA takes any similar regulatory action regarding the possible Aranesp side effects of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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