

Important Communications ^[1]

Zarxio submission is cancelled

Sandoz Canada has decided not to pursue its submission for biosimilar filgrastim (Zarxio®) in Canada at this time. This decision is due to specific requirements from Health Canada that were not present in our initial application. Zarxio is our proposed formulation of filgrastim and is being developed by Sandoz as an important treatment option for Canadian patients with neutropenia.

We are disappointed with this setback in bringing Zarxio to Canadian patients. With 10 years of experience around the globe, we are confident that Zarxio is a product that meets stringent safety, efficacy and quality standards. It was approved by the European Commission (in 2009) and the FDA (in 2015) and is currently marketed in 86 countries, accounting for over 27 million filgrastim patient exposure day¹

We remain committed to bringing this product to patients in Canada and we are evaluating how to best meet the requirements of Health Canada. We are determined to work closely with them to make this a reality as soon as possible.

Furthermore, we stand behind our commitment to bringing high-quality biosimilar medicines to Canadian patients to help fulfill their unmet needs

1 Sandoz data on file.

Jul 25, 2019

Recall of Ranitidine medicines - [click here to open the Pharmacy Notice](#) ^[2]

As a precautionary measure, Sandoz is recalling at pharmacy level several batches of Sandoz Ranitidine film-coated tablets across a number of markets, including Canada.

[Direct Pharmacy Drug Recall Form - Sandoz Ranitidine](#) ^[3]

Jul 25, 2019

Important Safety Information on Tacrolimus - [click here to open PDF](#) ^[4]

Risk of graft rejection due to medication errors: Inadvertent switching between different oral formulations.

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Links

[1] <https://www.sandoz.ca/en/important-communications>

[2]

[https://www.sandoz.ca/sites/www.sandoz.ca/files/Ranitidine%20%20SDZ_Direct%20Pharmacy%20Letter%20Type%](https://www.sandoz.ca/sites/www.sandoz.ca/files/Ranitidine%20%20SDZ_Direct%20Pharmacy%20Letter%20Type%20A.pdf)

[3]

https://www.sandoz.ca/sites/www.sandoz.ca/files/Direct%20Pharmacy%20Ranitidine%20_Drug%20recall%20form.x

[4] <https://www.sandoz.ca/sites/www.sandoz.ca/files/11667->

[Important%20Safety%20Information%20on%20Tacrolimus.pdf](https://www.sandoz.ca/sites/www.sandoz.ca/files/11667-Important%20Safety%20Information%20on%20Tacrolimus.pdf)