



Company Statement

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ORGANON CANADA CONFIRMS NO QUALITY ISSUE FOR PROMETRIUM®

Kirkland, Quebec – January 22, 2024 – Following an investigation regarding complaints of underfilled and/or hardened capsules of PROMETRIUM® initiated by Organon Canada, a subsidiary of Organon (NYSE: OGN), a global healthcare company with a focus on women’s health, the information to date concludes no evidence of product quality issues was found for PROMETRIUM®. An investigation report with findings to date has been submitted to Health Canada. The investigation findings to date show that PROMETRIUM® meets all quality specifications and are in accordance with applicable laws, including current good manufacturing practices (cGMPs).

Nothing is more important to Organon than the safety of the patients who use our products, and so we work to ensure that the efficacy, safety, and quality of our medicines meet all applicable standards. As per our standard procedure regarding potential quality complaints, Organon Canada began investigating claims of underfilled and/or hardened capsules of PROMETRIUM® as soon as the first patient complaint was reported to the company, in December 2023.

PROMETRIUM® should be stored at temperatures between 15-30°C and protected from light as recommended by the product monograph.¹

Patients should take the PROMETRIUM® capsules as prescribed by their healthcare provider and in accordance with the product monograph. To help ensure patients receive the prescribed dose of PROMETRIUM®, each 100 mg capsule should be taken orally and, in its entirety, as directed by a patient's healthcare provider and consistent with the product monograph. If a patient has any concerns or additional questions as to how to take PROMETRIUM®, they should be advised to speak with their healthcare professional.

Organon is dedicated to the safety of patients who take our products and has agreements in place with its manufacturer that requires that PROMETRIUM® is manufactured in accordance with applicable laws, including current good manufacturing practices (cGMPs), as well as the specifications for PROMETRIUM®. Reports of product quality complaints and/or adverse events are taken seriously and, as with all of our medicines, we continually monitor the quality and safety of PROMETRIUM®.

About Organon

Organon is a global healthcare company formed to focus on improving the health of women throughout their lives. Organon offers more than 60 medicines and products in women's health in addition to a growing biosimilars business and a large franchise of established medicines across a range of therapeutic areas. Organon's existing products produce strong cash flows that support investments in innovation and future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, connect with us on [LinkedIn](#).

Reference: 1. PROMETRIUM® Product Monograph. Organon Canada Inc., March 29, 2021.
Available at: https://www.organon.com/canada-en/prometrium-pm_e

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