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Health Canada Approves NDUVRA™ (Tapinarof Cream), 1%, for the Topical Treatment of Plaque Psoriasis in Adults

Kirkland, Quebec, April 14, 2025 – Organon Canada, a global healthcare company with a mission to improve the health of women throughout their lives, today announced that Health Canada has approved NDUVRA (tapinarof cream), 1%, the first in a novel class of aryl hydrocarbon receptor agonists to be approved in Canada, for the topical treatment of plaque psoriasis in adults.¹

“The approval of NDUVRA (tapinarof cream) introduces a new treatment option for adult patients with mild to severe plaque psoriasis. In clinical trials, patients who achieved complete disease clearance discontinued treatment and experienced a sustained median response for approximately four months,” said Michael Casia, President and Managing Director, Organon Canada. “Organon Canada is pleased to expand its existing and growing dermatology portfolio through the addition of tapinarof, bringing a novel treatment option to the most common form of psoriasis.”²

The approval of NDUVRA is based on the results from two randomized, double-blind, multicenter, vehicle-controlled trials conducted to evaluate the safety and efficacy of tapinarof cream for the treatment of adults with plaque psoriasis (symptoms varying from mild to severe).

Tapinarof is a cream that is applied once daily to affected areas. It may be used on all skin surfaces, including the head, neck, and intertriginous areas.

Tapinarof, known as VTAMA® outside of Canada, became part of the Organon portfolio in October 2024 as part of the company’s acquisition of Dermavant, with Canada representing the second country to approve the product worldwide.

About the tapinarof clinical studies

Tapinarof demonstrated significant improvement in the primary and secondary efficacy endpoints compared to vehicle cream in the PSOARING 1 and PSOARING 2 pivotal studies.

The primary efficacy endpoint in PSOARING 1 (DMVT-505-3001) and PSOARING 2 (DMVT-505-3002) in adults with plaque psoriasis was the proportion of patients who achieved treatment success, defined as a Physician Global Assessment (PGA) score of “Clear” (0) or “Almost Clear” (1) and at least a 2-grade improvement from baseline to Week 12. PGA treatment success was observed in 35% and 40% of patients using tapinarof in trials 1 and 2 vs 6% for patients using vehicle cream in both trials ($p < 0.001$). Secondary efficacy endpoints included PASI-75 (improvement of at least 75% in PASI score from baseline), change from baseline in %BSA, and PASI-90 (improvement of at least 90% in PASI score from baseline) at Week 12. The adverse event (AE) profile of tapinarof cream reported in both PSOARING 1 and PSOARING 2 demonstrated that the majority of AEs were localized to the site of application and were mild to moderate in nature. The most common AEs of subjects treated with tapinarof cream were folliculitis, nasopharyngitis, and contact dermatitis.

Following 12 weeks of treatment in PSOARING 1 or PSOARING 2, eligible patients could receive an additional 40 weeks of treatment in an open-label extension trial (PSOARING 3) to evaluate tapinarof cream for long-term safety and maintenance of response. Patients entering with a PGA = 0 had treatment discontinued and were followed for durability of treatment (remittive response). In this long-term extension study, of the 74 patients who entered with clear skin (PGA=0), the median time off therapy before experiencing PGA ≥ 2 was 115 days ($n=57$); 95% CI: 85, 162.

For more information about NDUVRA (tapinarof cream), including important safety information, visit https://pdf.hres.ca/dpd_pm/00080148.PDF.

About Plaque Psoriasis^{2,3}

Psoriatic disease includes various chronic, debilitating conditions that impacts more than one million people in Canada, with plaque psoriasis being the most prevalent type, affecting around 90% of patients. Symptoms can vary from mild to severe and usually consists of elevated patches that range from red to violet, often covered with flaking, silvery scales.

About Organon

Organon is an independent global healthcare company with a mission to help improve the health of women throughout their lives. Organon's diverse portfolio offers over 70 medicines and products in women's health, biosimilars, and a large franchise of established medicines across a range of therapeutic areas. In addition to Organon's current products, the company invests in innovative solutions and research to drive future growth opportunities in women's health and biosimilars. Organon is also pursuing opportunities to collaborate with biopharmaceutical partners and innovators who look to commercialize their products by leveraging Organon's scale and agile presence in fast growing international markets.

Organon has geographic scope with significant reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey, and a Canadian head office located in Kirkland, Quebec.

For more information, visit <https://www.organon.com/canada-en/> and connect with us on [LinkedIn](#).

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¹ NDUVRA Product Monograph. 2025

² https://www.canadianpsoriasis.ca/images/PsoSerious_2024/2024_PSO_Serious_Report_EN_Oct28v2.pdf

³ <https://dermatology.ca/public-patients/diseases-conditions/skin-conditions/psoriasis/>