



FOR IMMEDIATE RELEASE

Sun Pharma Announces Health Canada Approval of ^{Pr}WINLEVI[®] (clascoterone cream 1%) for Topical Treatment of Acne

- ***WINLEVI is the first and only topical Androgen Receptor Inhibitor, and the newest Health Canada-approved formulation to target the hormonal component of acne in 40 years.***
- ***WINLEVI may reduce sebum and decreases inflammation for male and female acne patients, 12 years of age and older.***

MUMBAI, India and BRAMPTON, ON, June 19, 2023 - Sun Pharma Canada Inc., a wholly owned subsidiary of Sun Pharmaceutical Industries Limited (Reuters: SUN.BO) (Bloomberg: SUNP IN) (NSE: SUNPHARMA) (BSE: 524715), "Sun Pharma" is pleased to announce Health Canada's approval of ^{Pr}WINLEVI (clascoterone cream 1%). WINLEVI is the first and only androgen receptor inhibitor indicated for the topical treatment of acne vulgaris (acne) in patients 12 years of age and older, and the newest Health Canada-approved formulation to target the hormonal component of acne for Canadian patients in 40 years.¹

"Acne is a common condition due to hormonal triggers. However, there has been a gap in topical acne treatments which impact the hormonal cascade of acne for Canadians," said Dr. Jerry K.L. Tan, dermatology specialist and founder of The Healthy Image Center in Windsor, Ontario. "I am thrilled that acne patients will soon have a new treatment option."

"Sun Pharma is committed to providing innovative dermatology medicines for Canadians, which fill the gap for necessary treatment options," said Abhay Gandhi, North America CEO of Sun Pharma. "We are thrilled to provide a new topical treatment option for the millions of Canadians affected by acne."

Acne is a highly prevalent dermatological condition, affecting approximately 20 per cent of Canadians.² Data shows that acne affects patients' health-related quality of life and may increase the risk of depression and anxiety.^{3, 4, 5}

"Our recent report, [*Breaking Out: a report on the acne patient experience in Canada*](#), uncovers substantial treatment gaps for individuals with acne," said Sue Sherlock, executive director of the Acne and Rosacea Society of Canada. "One of our top recommendations for the industry has been to increase access to more treatments. We are pleased to see a new product available for Canadian patients."

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WINLEVI is thought to inhibit the effects of androgen receptors in cells of the sebaceous glands (oil-producing glands in the skin) to help reduce sebum (oil) production and inflammatory cytokines,^{1, 6} and thus inhibits the androgen cascade.

Instead of a topical approach to acne treatment that focuses on follicular hyperkeratinization, reducing inflammation or exerting antibacterial effects, WINLEVI targets the androgen receptor in the skin to tackle sebum production and inflammation.¹

WINLEVI will be available in Canada this Fall. For more information visit www.sunpharma.com/canada or call 1-833-388-0532.

About PrWINLEVI (clascoterone cream 1%)

WINLEVI is approved for the topical treatment of acne vulgaris in people 12 years of age and older. Although the exact mechanism of action for WINLEVI is unknown, laboratory studies suggest the active ingredient, clascoterone, competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.⁷

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production.⁸ Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation.⁹ In particular, the skin of patients with acne vulgaris produces higher levels of the androgens testosterone and dihydrotestosterone (DHT) than the skin of healthy individuals.¹⁰ Current oral hormonal therapies have been shown to be effective in treating acne regardless of whether androgen levels are elevated.⁸ However, whereas certain oral hormonal therapies are recommended for use in some female patients with acne, their use in males has been limited due to the potential risk of systemic side effects such as gynecomastia (overdevelopment or enlargement of breast tissue) and the inability to grow a beard.^{1, 8}

WINLEVI binds to the androgen receptor competing with androgens such as DHT on cells within the sebaceous gland. Although its precise mechanism of action is unknown, studies suggest WINLEVI inhibits androgen receptors in the skin and reduces production of sebum and inflammation.^{6, 9}

Additionally, WINLEVI is rapidly metabolized in the skin, limiting systemic absorption.^{11, 12}

In clinical studies, a 12-week course of WINLEVI therapy was associated with significant reductions in both inflammatory and noninflammatory lesions, as well as a significant increase in the number of patients achieving treatment success when compared to vehicle.⁶

In two Phase 3 clinical studies, 18.8% and 20.9% of WINLEVI-treated patients achieved success based on IGA at Week 12, compared with 8.7% and 6.6% of patients receiving vehicle ($P < 0.001$). The mean absolute change from baseline in NILCs at Week 12 was -20.4 and -19.5 for patients treated with WINLEVI, versus -13.0 and -10.8 for vehicle-treated patients ($P < 0.001$). The mean absolute change from baseline in ILCs at Week 12 was -19.3 and -20.1 in the WINLEVI groups, compared to -15.4 and -12.6 in the two studies' vehicle groups ($P < 0.01$).⁶

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There were no adverse events reported as an adverse drug reaction in > 1% of patients. Most local skin reactions (LSRs) were trace or mild in severity and occurred in a similar percentage of patients treated with vehicle. The most frequently reported LSRs were erythema (redness) and scaling/dryness.⁶

WINLEVI is supplied in 30-gram aluminum tubes. Each gram of WINLEVI contains 10 mg of clascoterone in a white to almost white cream. Patients are instructed to cleanse the affected area gently, and after the skin is dry, to apply a thin even layer of WINLEVI over the area prone to acne, twice a day, in the morning and in the evening.

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About Sun Pharma Canada Inc.

Sun Pharmaceutical Industries Limited is growing its presence in Canada, bringing together the power of a global network with localized research and care to address the unmet needs of Canadian patients and healthcare providers.

Sun Pharma Canada Inc., a wholly owned subsidiary of Sun Pharmaceutical Industries Limited, is focused on providing innovative medicines in dermatology and ophthalmology, bringing greater access and support for patients.

Patients and healthcare providers are at the centre of everything and Sun Pharma's "passion is clear". Sun Pharma's commitment to listening, acting and caring means the team is able to respond to distinct needs and provide personalized care, while addressing important gaps in treatment and quality of life.

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Sun Pharma offers a wide range of affordable medicines for the Canadian population. Together with Taro Pharmaceutical Industries Ltd. (a subsidiary of Sun Pharma) these complementary companies bring together capabilities in specialty and niche segments coupled with a presence in the top 15 Canadian generic products.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across six continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6% of annual revenues in R&D. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

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