

# Health Canada Approves (Pr)CABTREO(TM) (clindamycin phosphate, adapalene and benzoyl peroxide) Triple-Combination Topical Treatment for Acne Vulgaris in Patients 12 Years of Age and Older

2024-09-11

LAVAL, QC / ACCESSWIRE / September 11, 2024 / Bausch Health, Canada Inc., part of Bausch Health Companies Inc. (NYSE:BHC)(TSX:BHC) today announced the approval by Health Canada of PrCABTREOTM (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1%, a new triple-combination topical prescription treatment for acne vulgaris in patients 12 years of age and older.<sup>1</sup>

CABTREO is the first and only triple-combination topical treatment for acne approved by Health Canada with three mechanisms of action - an antibiotic, a retinoid and an antibacterial agent - to provide a safe and effective treatment.<sup>1</sup>

"The approval of CABTREO shows the continuing commitment of Bausch Health to bring innovative dermatology treatments to Canadians," said Amy Cairns, Vice-President, Commercial and General Manager, Canada, Bausch Health. "We are proud to offer this first triple-combination topical acne treatment to millions of Canadians who suffer from acne each year."

CABTREO is a topical gel that is administered by patients once daily to affected areas of their skin. Its active ingredients are the antibiotic clindamycin phosphate, the topical retinoid adapalene, and the oxidizing agent benzoyl peroxide which has a broad-spectrum anti-bacterial activity.<sup>1</sup>

"The unique triple combination provided by CABTREO has shown significant treatment success in studies, reducing

both the inflammatory and non-inflammatory skin lesions we associate with acne," said Dr. Jerry Tan, MD, FRCPC, a dermatologist in Windsor, Ontario, and Adjunct Professor at Western University in London, Ontario. "The convenient once-daily dosing of CABTREO will also be important to many patients."

CABTREO will be made available through pharmacies across Canada in the fourth quarter this year.

"People with acne are always hopeful and excited when there is a new approved treatment in Canada that might help them," said Sue Sherlock, Executive Director of the Acne and Rosacea Society of Canada. "Acne can significantly impact the emotional and social well-being of sufferers so having effective treatments is important to them."

#### About Acne Vulgaris

Acne vulgaris ("vulgaris" means "common") is the most common skin problem seen by doctors in Canada. It occurs when the pores of the skin become plugged with oil and skin cells, often causing whiteheads, blackheads, pimples or cysts to appear on the face, forehead, chest, upper back and shoulders. Acne affects about 5.6 million Canadians, or nearly 20 per cent of the population, including about 90 per cent of adolescents. About 25 per cent of teens will still have acne at age 25. Acne causes emotional distress and can cause permanent scarring.<sup>2</sup> It can also cause skin pigmentation changes.<sup>3</sup>

#### CABTREO Clinical Data and Safety Information

CABTREO was studied in two phase 3 multicentre, randomized, placebo controlled clinical trials in 363 patients with acne vulgaris. Both studies met all co-primary efficacy endpoints, including absolute change from baseline in inflammatory lesion count, absolute change from baseline in non-inflammatory lesion count, and percentage of patients achieving pre-defined treatment success. Combined efficacy results for both trials for CABTREO achieved approximately 50% treatment success and a greater than 70% reduction in both inflammatory and noninflammatory lesions at Week 12.<sup>1</sup>

The most frequent adverse reactions that may occur with CABTREO are mild to moderate application site reactions, such as skin irritation characterized by scaling, dryness, erythema, and burning/stinging. CABTREO should not be used by those who are hypersensitive to any of the ingredients in it (clindamycin phosphate, adapalene, benzoyl peroxide and others), patients with a history of regional enteritis (Crohn's disease), ulcerative colitis or antibiotic-associated colitis or by pregnant women and women planning a pregnancy. CABTREO may bleach hair and coloured fabric so caution should be used when applying it near the hairline.<sup>1</sup>

Health Canada has not authorized CABTREO for pediatric use under the age of 12 years. CABTREO is for topical use only and is not for oral, ophthalmic use or intravaginal use.<sup>1</sup>

#### About Dermatology at Bausch Health, Canada

Bausch Health, Canada has one of the largest prescription dermatology businesses in Canada dedicated to helping patients in the treatment of a range of therapeutic areas, including psoriasis, actinic keratosis, acne, atopic dermatitis and other dermatoses. The Bausch Health, Canada dermatology portfolio includes several leading acne, psoriasis, anti-fungal and corticosteroid-responsive dermatoses products.

CABTREO is the fourth new dermatology treatment from Bausch Health, Canada approved by Health Canada and made available to Canadians over the past four years, adding to the company's leading portfolio in this important treatment area. The other approvals were for ARAZLO™ (tazarotene) lotion, 0.045% w/w, for the topical treatment of acne vulgaris in patients 10 years of age and older; BRYHALI™ (halobetasol propionate lotion 0.01% w/w), for corticosteroid-responsive dermatoses and the topical treatment of plaque psoriasis; and DUOBRII™ (0.01% w/w halobetasol propionate and 0.045% w/w tazarotene) to treat adults with moderate to severe plaque psoriasis.<sup>4</sup>

All four treatments - CABTREO, ARAZLO, BRYHALI and DUOBRII - are manufactured at Bausch Health's Laval, Quebec, facility for Canada and the United States.

#### About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX:BHC) is a global diversified pharmaceutical company enriching lives through our relentless drive to deliver better health care outcomes. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, medical aesthetic devices, international pharmaceuticals and eye health, through our controlling interest in Bausch + Lomb. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. For more information, visit [www.bauschhealth.com](http://www.bauschhealth.com) and connect with us on [LinkedIn](#).

The Bausch Health Canadian prescription treatment portfolio is focused on dermatology, gastrointestinal and cardio-metabolic conditions. Bausch Health also has two manufacturing facilities for prescription pharmaceuticals in Canada: in Laval, Quebec, and Steinbach, Manitoba. More information can be found at the Company's website at [www.bauschhealth.ca](http://www.bauschhealth.ca).

#### Forward-looking Statements

This news release may contain forward-looking statements within the meaning of applicable securities laws, including the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements may generally be identified by the use of the words "will," "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions. These statements are neither historical facts nor assurances of future performance, are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Actual results are subject to

other risks and uncertainties that relate more broadly to Bausch Health's overall business, including those more fully described in Bausch Health's most recent annual and quarterly reports and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. The Company undertakes no obligation to update any of these forward-looking statements to reflect events, information or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

## REFERENCES

- 1 Bausch Health, Canada Inc., CABTREO Product Monograph, [https://pdf.hres.ca/dpd\\_pm/00076715.PDF](https://pdf.hres.ca/dpd_pm/00076715.PDF).
- 2 Canadian Dermatology Association, Acne, Quick Facts, <https://dermatology.ca/public-patients/skin/acne/#:~:text=Acne%20affects%205.6%20million%20Canadians,adults%20ages%2020%20to%2040>, accessed Aug. 20, 2024.
- 3 "What to Know about Hyperpigmentation Acne." Medical News Today, Jessica Caporuscio, April 28, 2021, <https://www.medicalnewstoday.com/articles/hyperpigmentation-acne>, accessed Aug. 20, 2024.
- 4 Bausch Health, Canada Inc., Canadian Product List, <https://bauschhealth.ca/products/canadian-product-list/>.

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SOURCE: Bausch Health Companies Inc.

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