BAUSCH Health

FDA Approves Cabtreo™ (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel For The Treatment Of Acne Vulgaris In Patients Twelve Years Of Age And Older

October 20, 2023

First and only FDA-approved fixed-dose, triple-combination topical treatment

LAVAL, Quebec, Oct. 20, 2023 – Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and its dermatology business, Ortho Dermatologics, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application for CABTREOTM (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1%, indicated for the topical treatment of acne vulgaris in patients twelve years of age and older. CABTREO is the first and only FDA-approved fixed-dose, triple-combination topical treatment for acne. CABTREO is expected to be available to patients in Q1 2024.

"With today's approval of CABTREO, millions of Americans who suffer from acne each year have a new triple-combination topical acne treatment," said Thomas J. Appio, Chief Executive Officer, Bausch Health. "Acne treatment often requires using multiple products and dosing regimens, which can pose a number of challenges for patients. CABTREO has the potential to simplify dosing with a once daily topical acne treatment regimen."

CABTREO offers three mechanisms of action, combining an antibiotic, retinoid and antibacterial, to provide a proven, safe and effective treatment.

"While most acne treatments currently available utilize multiple therapies and regimens, we are excited to see that the triple combination in CABTREO has resulted in significant treatment success and reduction in both the inflammatory and noninflammatory lesions typically associated with acne," said Julie C. Harper, MD., Dermatology & Skin Care Center of Birmingham, Birmingham, AL. "With the approval of CABTREO, physicians can now offer patients an acne treatment that has the potential to be a simple, once daily dosing option."

CABTREO Comprehensive Clinical Data

CABTREO was studied in two Phase 3 multicenter, 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 treatment success (2 grade reduction of the EGSS (evaluators global severity score) from baseline with an EGSS score of clear (0) or almost clear (1)).

Combined efficacy results for both trials for CABTREO achieved approximately 50% treatment success and approximately 75% reduction in both inflammatory and noninflammatory lesions at Week 12.

In Study 1, 49.6% of participants achieved treatment success with CABTREO compared to 24.9% with vehicle. Mean percent reduction for inflammatory lesions was 75.7% (27.7 mean absolute reduction) vs. 59.6% (21.7 mean absolute reduction) with vehicle. Mean percent reduction for non-inflammatory lesions was 72.7% (35.4 mean absolute reduction) vs. 47.6% (23.5 mean absolute reduction) with vehicle.

In Study 2, 50.5% of participants achieved treatment success with CABTREO compared to 20.5% with vehicle. Mean percent reduction for inflammatory lesions was 80.1% (30.1 mean absolute reduction) vs. 56.2% (20.8 mean absolute reduction) with vehicle. Mean percent reduction for non-inflammatory lesions was 73.3% (35.2 mean absolute reduction) vs. 49.0% (22.0 mean absolute reduction) with vehicle.

The most common adverse reactions (occurring in >1% of the CABTREO group and greater than the vehicle group) were application site reactions, pain, erythema, dryness, irritation, exfoliation, and dermatitis.

About Acne Vulgaris

Acne is the most common skin problem in the United States, which occurs when hair follicles become obstructed with sebum and skin cells, resulting in the formation of whiteheads, blackheads, or pimples on the face, forehead, chest, upper back and shoulders.1,2 Up to 50 million Americans have acne.2 Depending on its severity, acne can cause emotional distress and scar the skin.2

What is CABTREO?

CABTREO (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1% is a prescription medicine used on the skin only (topical use) to treat acne vulgaris in adults and children 12 years of age and older. Do not use CABTREO in your mouth, eyes, or vagina.

IMPORTANT SAFETY INFORMATION

Before using CABTREO, tell your healthcare provider about all your medical conditions, including if you: plan to have surgery, are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, have other skin problems, including cuts, abrasions, sunburn, or eczema; or use other skin and topical acne products that may increase the irritation of your skin when used with CABTREO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the- counter medicines, vitamins, herbal supplements, and if you take or use a medicine that contains erythromycin. CABTREO should not be used with products that contain erythromycin.

Do not use CABTREO if you have had an allergic reaction to clindamycin, adapalene, benzoyl peroxide, lincomycin, or any of the ingredients in CABTREO or have Crohn’s disease, ulcerative colitis, inflammation of the colon (colitis), or severe diarrhea with antibiotic use.

What should I avoid while using CABTREO?

- Avoid or limit your time in sunlight, including use of sunlamps or tanning beds during treatment with CABTREO as it can make you more sensitive, and you could get severe sunburn. Use sunscreen and wear clothes including a hat that covers the treated areas of your skin if you have to be in sunlight.
- Cold weather and wind may irritate skin treated with CABTREO.

- Avoid applying CABTREO to areas with skin problems including, cuts, abrasions, sunburned skin, or eczema.
- Avoid skin products that may dry or irritate your skin.
- Avoid the use of "waxing" as a hair removal method on skin treated with CABTREO.

What are the possible serious and most common side effects of CABTREO?

Tell your doctor right away if you experience side effects, including:

- **Allergic reactions:** Stop using CABTREO if you have hives, rash, severe itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, throat tightness, feeling faint, dizzy, or lightheaded.
- **Inflammation of the colon (colitis):** Stop using CABTREO if you have severe stomach (abdominal) cramps, watery diarrhea, or bloody diarrhea during treatment, and within several weeks after treatment with CABTREO.
- **Sensitivity to sunlight. See "What should I avoid while using CABTREO".**
- **Skin irritation** at the application site is common with CABTREO and may include redness, scaling, dryness, stinging, burning, itching, and swelling.

These are not all the possible side effects of CABTREO. Call your doctor for medical advice about side effects. You may report side effects to Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA- 1088 or
www.fda.gov/medwatch

Please click
here
for full Prescribing Information, Patient Information and Instructions for Use.

About Ortho Dermatologics
Ortho Dermatologics is one of the largest prescription and aesthetic dermatology businesses dedicated to helping patients in the treatment of a range of conditions, including psoriasis, onychomycosis, actinic keratosis, acne, atopic dermatitis and other dermatoses. More information can be found at
www.ortho-dermatologics.com
.

About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global diversified pharmaceutical company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our controlling ownership interest in Bausch + Lomb. With our leading durable brands, we are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit
www.bauschhealth.com
and connect with us on
Twitter
and
LinkedIn
.

References

- American Academy of Dermatology. (2020). Skin conditions by the numbers. Retrieved from https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers

. Accessed March 13, 2023.

- Mayo Clinic. (2020). Acne. Retrieved from https://www.mayoclinic.org/diseasesconditions/acne/symptoms-causes/syc-20368047 . Accessed March 13, 2023.

###

CABTREO™ is a trademark of Ortho Dermatologics' affiliated entities.
Ortho Dermatologics is a trademark of Ortho Dermatologics' affiliated entities.
© 2023 Ortho Dermatologics' affiliated entities.
CAB.0055.USA.23

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE