APMA Grants Seal of Approval for JUBLIA® (efinaconazole) Topical Solution, 10%

December 06, 2021

LAVAL, QC, Dec. 6, 2021 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced JUBLIA® (efinaconazole) Topical Solution, 10%, a treatment for onychomycosis, a fungal infection of the toenails, has received the American Podiatric Medical Association (APMA) Seal of Approval. The APMA Seal of Approval is granted to products that promote good foot health and are of significant value when used in a consistently applied program of daily foot care and regular professional treatment.



"We are pleased to receive this distinguished honor by the APMA, the leading professional organization for the more than 12,500 podiatrists in the United States," said Joseph C. Papa, chairman and CEO, Bausch Health. "The APMA Seal of Approval recognizes the demonstrated safety and efficacy profile of JUBLIA® and its continued use as a valuable treatment option for adults and children with toenail fungal infections. Since its initial approval to treat adults in 2014 and subsequent approval to treat pediatric patients six years of age and older in 2020, JUBLIA® has been available to help podiatrists and patients struggling with onychomycosis."

To earn the APMA Seal of Approval, products must undergo a rigorous scientific review by a committee of APMA podiatrists. The comprehensive review includes objective data from clinical and laboratory studies, patents and quality control, as well as details of intended use and product composition. Following a detailed review of the product by each committee member, a

recommendation is sent to the APMA Board of Trustees, which either accepts or rejects the recommendation.

"Toenail fungus is extremely common, but it is an infection—and a highly contagious infection," said Jeffrey R. DeSantis, DPM, FACFAS, president of the American Podiatric Medical Association. "APMA is proud to bestow its Seal of Approval on products such as JUBLIA® that meet our physicians' highest standards for safety and effectiveness."

For more information on JUBLIA®, visit
http://www.jubliarx.com/
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Important Safety Information for JUBLIA® (efinaconazole) Topical Solution, 10%

INDICATION
JUBLIA® (efinaconazole) Topical Solution, 10% is a prescription medicine used to treat fungal infections of the toenails.

IMPORTANT SAFETY INFORMATION

- JUBLIA® is for use on nails and surrounding skin only. Do not use JUBLIA® in your mouth, eyes, or vagina. Use it exactly as instructed by your doctor.
- The safety and efficacy of JUBLIA® have not been established in children under six years old.
- Before you use JUBLIA®, tell your doctor about all your medical conditions, including if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed, because it is not known whether JUBLIA® can harm an unborn fetus or nursing infant.
- Tell your doctor about all medications you are taking, and whether you have any other nail infections.
- JUBLIA® is flammable. Avoid heat and flame while applying JUBLIA® to your toenail.
- JUBLIA® may cause irritation at the treated site. The most common side effects include: ingrown toenail, redness, itching, swelling, burning or stinging, blisters, and pain. Tell your doctor about any side effects that bother you or do not go away.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or visit
www.fda.gov/medwatch
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Please click
here
for full Prescribing Information, including Patient Information.

Visit
www.jubliarx.com
to learn more.

About Onychomycosis
Onychomycosis is a common condition, caused predominantly by various fungal organisms (fungi), and typically occurs under the toenail, though fingernails may also be affected. The condition typically begins as a small white or yellow spot beneath the nail, and causes nail discoloration, thickening and/or distortion and irregular surface changes. A severe case of nail fungus can be painful and may cause permanent nail damage.[1]

About APMA
The American Podiatric Medical Association (APMA) is the nation's leading professional organization for today's podiatrists. Doctors of Podiatric Medicine (DPMs) are qualified by their education, training, and experience to diagnose and treat conditions affecting the foot, ankle, and structures of the leg. APMA has 53 state component locations across the United States and its territories, with a membership of more than 12,500 podiatrists. All practicing APMA members are licensed by the state in which they practice podiatric medicine. For more information, visit www.apma.org
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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 therapeutic areas, including psoriasis, actinic keratosis, acne, atopic dermatitis and other dermatoses. The Ortho Dermatologics portfolio also includes several leading medical device systems for aesthetic applications, such as skin tightening and resurfacing, laser hair removal and preventative therapeutic skin care treatments. More information can be found at
www.ortho-dermatologics.com
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About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. 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
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Forward-looking Statements
This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements 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. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in Bausch Health's most recent annual report on Form 10-K 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. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, launches and costs (which may increase). 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. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

References
1. Mayo Clinic. "Nail Fungus." Retrieved from: https://www.mayoclinic.org/diseases-conditions/nail-fungus/symptoms-causes/syc-20353294 . Accessed Dec. 2, 2021.

JUBLIA is a trademark of Ortho Dermatologics' affiliated entities.
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