

US WorldMeds and Salix Announce U.S. Launch of LUCEMYRA™ (lofexidine) 0.18 Mg Tablets

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LOUISVILLE, Ky. and BRIDGEWATER, N.J., Aug. 6, 2018 /PRNewswire/ -- US WorldMeds, LLC, and Salix Pharmaceuticals, a wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced the U.S. launch and availability of LUCEMYRA™ (lofexidine) 0.18 mg tablets, the first and only non-opioid medication indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

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<https://www.multivu.com/players/English/8314851-us-world-meds-lucemyra-fda-approval/>

The Centers for Disease Control and Prevention estimates that more than 115 people in the U.S. die each day from opioid overdose.¹ Often overlooked, opioid withdrawal is one of the most powerful barriers keeping people from discontinuing opioids. Many people have such difficulty tolerating symptoms of withdrawal that the desire to avoid them can perpetuate their opioid use.² In a survey of people with chronic pain, 57 percent of patients reported avoidance of withdrawal as the primary reason for continued use of prescription opioids.³

"Many people who wish to stop taking opioids are searching for a treatment that will help get them through the agonizing symptoms of withdrawal," said P. Breckinridge Jones, chief executive officer and founder, US WorldMeds. "The availability of LUCEMYRA broadens the range of evidence-based pharmacological options available to healthcare providers, so they can manage the challenges of withdrawal and facilitate their patients' abrupt discontinuation of opioids."

The FDA approved LUCEMYRA in May 2018. The product's development involved a grant from and close collaboration with the National Institute on Drug Abuse, part of the National Institutes of Health. In June, US WorldMeds and Salix Pharmaceuticals entered into an exclusive co-promotion agreement for LUCEMYRA. Today, Salix and US WorldMeds have initiated sales force efforts in the promotion of LUCEMYRA to primary care physicians, pain management specialists, psychiatrists focused on addiction medicine and addictionologists.

"LUCEMYRA addresses a large and growing need in the field of primary care and pain management. Opioid withdrawal is frequently overlooked and can present a significant challenge in the discontinuation of opioid-based pain medications. By effectively intervening during withdrawal and helping to control severe, disabling withdrawal symptoms, LUCEMYRA can help provide a starting point toward recovery," said Mark McKenna, president, Salix Pharmaceuticals. "We share US WorldMeds' enthusiasm and confidence that LUCEMYRA can help the millions who develop Opioid Withdrawal Syndrome find meaningful relief."

The launch includes a co-pay program that provides LUCEMYRA to eligible patients for as little as \$25.[†] Most pharmacies across the country are covered through the program.

Physicians, pharmacists or other healthcare providers with questions about LUCEMYRA should contact 1-833-LUCEMYRA or visit

www.lucemyra.com

LUCEMYRA is not an opioid drug and is not a treatment for Opioid Use Disorder (OUD) (sometimes known as opioid addiction). For people who have been diagnosed with OUD, withdrawal management alone, with or without LUCEMYRA, is not recommended; LUCEMYRA should be used as part of a comprehensive management program created by a healthcare provider.

Indications

LUCEMYRA is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

Important Safety Information for Patients

- LUCEMYRA will not stop you from craving opioids.
- LUCEMYRA is not an opioid and will not produce the effects seen when taking opioids.
- LUCEMYRA may lessen the severity of symptoms, but it may not completely prevent them.

After a period of not using opioids, you may be more sensitive to the effects of lower amounts of opioids. Taking opioids in amounts that you used before stopping opioid use, whether with or without LUCEMYRA, can lead to overdose and death. It is important that you, your family, and the people closest to you are aware of this increased risk of overdose.

Alcohol, barbiturates, and benzodiazepines should be used with caution while taking LUCEMYRA as serious side effects may occur.

Tell your healthcare provider if you have ever been diagnosed with kidney disease or liver disease.

LUCEMYRA may cause low blood pressure or slower heart rate. Tell your healthcare provider if you have ever been diagnosed with low blood pressure, slow heart rate, any other cardiac abnormality (including prior diagnosis or family history of long QT syndrome), or if you have had a heart attack.

Tell your healthcare provider about all medications you are taking. LUCEMYRA should be used with caution with any medications that decrease pulse or blood pressure.

Watch for signs of a drop in your blood pressure or heart rate, including dizziness, lightheadedness, or feelings of faintness either when sitting or if you quickly stand up. If you experience these symptoms, call your healthcare provider and do not take your next dose of LUCEMYRA until you have talked to your healthcare provider.

It is important to stay hydrated while taking LUCEMYRA during opioid discontinuation or withdrawal.

The most common side effects seen with LUCEMYRA are low blood pressure or symptoms such as lightheadedness, slow heart rate, dizziness, sleepiness, and dry mouth.

Talk to your healthcare provider before taking other medications for individual symptoms of withdrawal (such as pain relievers, sleep aids, or medications for upset stomach). Your healthcare provider will tell you whether it is safe to take LUCEMYRA with other medications you may be prescribed during opioid discontinuation (such as buprenorphine/naloxone, methadone, naltrexone).

LUCEMYRA should not be stopped abruptly. Consult your healthcare provider before stopping or

reducing your LUCEMYRA dose.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-833-LUCEMYRA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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Please click

[here](#)

to access the full U.S. Prescribing Information and Patient Information for LUCEMYRA.

About LUCEMYRA (lofexidine)

LUCEMYRA (lofexidine), an oral tablet, is a central alpha 2-adrenergic agonist that reduces the release of norepinephrine to suppress the neurochemical surge that produces opioid withdrawal. It is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. In clinical trials, LUCEMYRA significantly reduced the severity of withdrawal symptoms compared to placebo, as reported by patients experiencing opioid withdrawal. LUCEMYRA is administered in three 0.18 mg tablets taken orally four times daily at five- to six-hour intervals during the period of peak withdrawal symptoms (generally five to seven days following last use of opioids); total treatment may continue for up to 14 days, with dosing guided by symptoms. LUCEMYRA should be discontinued with gradual dose reduction over two to four days.

About Opioid Withdrawal

Opioids lower norepinephrine, a brain chemical that supports vital functions like respiration and consciousness. With continued opioid use, the brain establishes a new equilibrium by increasing compensatory norepinephrine production in order to maintain normal functioning. When opioids are removed, or the dose is significantly reduced, the brain's increased norepinephrine levels are no longer offset by the presence of the opioids. This results in a norepinephrine surge that produces the acute and painful symptoms of withdrawal.

About US WorldMeds

US WorldMeds is a specialty pharmaceutical company whose products are making a difference in the lives of the patients and communities it serves. US WorldMeds takes an agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, US WorldMeds has global presence and more than 15 years of experience in the development, licensure, and commercialization of unique products. For more information about US WorldMeds, visit

<http://www.usworldmeds.com/>

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About Salix

Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm healthcare providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that

focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, New Jersey.

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. More information can be found at

www.bauschhealth.com

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[†]Patients whose prescriptions will be paid for in part or in whole by Medicare, Medicaid or any similar federal or state healthcare program are not eligible for savings or rebates according to federal and state law. Patients must visit a participating pharmacy for savings or rebates on their LUCEMYRA prescriptions. Maximum benefits may apply.

References

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US WorldMeds Media Contact:

Brittany Horowitz

Brittany.Horowitz@edelman.com

646-229-0213

US WorldMeds U.S. Medical Inquiries:

888-900-USWM (8796)

Bausch Health Investor Contact:

Arthur Shannon

Arthur.Shannon@bauschhealth.com

514-856-3855

877-281-6642 (toll free)

Bausch Health Media Contact:

Lainie Keller

Lainie.Keller@bauschhealth.com

908-927-0617

Salix Media Contact:

Karen Paff

Karen.Paff@salix.com

908-927-1190



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SOURCE US WorldMeds, LLC



Investor Inquiries

ir@bauschhealth.com

877-281-6642

514-856-3855 (Canada)

Media inquiries

Corporate.communications@bauschhealth.com

908-569-3692

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