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## Dr. Reddy's Laboratories announces USFDA final approval and launch of Buprenorphine and Naloxone Sublingual Film in the U.S. Market

Hyderabad, India, June 15, 2018

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. June 15, 2018— Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) announced today that it has received final approval from the U.S. Food and Drug Administration (USFDA) and is launching Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, a therapeutic equivalent generic version of Suboxone® (buprenorphine and naloxone) sublingual film, in the United States market. The product is being launched with an approved Risk Evaluation and Mitigation Strategy (REMS) Program.\*\*

Buprenorphine and naloxone are used to treat adults with opioid dependence/addiction. Buprenorphine helps suppress withdrawal symptoms caused by discontinuation of opioid drugs, and naloxone reverses and blocks the effect of opioids. This combination of medications is used as part of a complete treatment program including prescription monitoring, counseling, and psychosocial support.

In a statement released earlier today by the USFDA, Commissioner Scott Gottlieb, M.D., explained, "The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure these medicines are accessible to the patients who need them. That includes promoting the development of better drugs, and also facilitating market entry of generic versions of approved drugs to help ensure broader access."

"With opioid addiction becoming increasingly prevalent in America, the full approval and launch of our generic equivalent of Suboxone® could not have come at a more critical time to help patients," explains Alok Sonig, Chief Executive Officer, Developed Markets. "We are excited to be launching this important product that will help enable patients to prevail over this insidious disease."

Sonig adds. "This approval is an important milestone for our company and a testament to our commitment to bring affordable generic medicines to market for patients. Our company will continue to look for opportunities to acquire and manufacture assets that accelerate access to innovative and affordable medicines for patients."

The Suboxone® brand had U.S. sales of approximately \$1.86 billion MAT for the most recent twelve months ending in April 2018 according to IMS Health\*.

### Important Safety Information

#### What important information should I know about Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg?

Buprenorphine and Naloxone Sublingual Film can cause serious and life-threatening breathing problems. Call your doctor right away or get emergency help as these can be signs of an overdose or other serious problems:

- You feel faint, dizzy, or confused
- Your breathing gets much slower than is normal for you
- Buprenorphine and Naloxone Sublingual Film contains an opioid that can cause physical dependence.
- Do not stop taking Buprenorphine and Naloxone Sublingual Film without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medication.

- An overdose and even death can happen if you take benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol while using Buprenorphine and Naloxone Sublingual Film. Ask your doctor what you should do if you are taking one of these.
- Do not inject Buprenorphine and Naloxone Sublingual Film.
- Injecting Buprenorphine and Naloxone Sublingual Film may cause life-threatening infections and other serious health problems.
- Injecting Buprenorphine and Naloxone Sublingual Film may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.
- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with Buprenorphine and Naloxone Sublingual Film.

### **Who should not use Buprenorphine and Naloxone Sublingual Film?**

Do not take Buprenorphine and Naloxone Sublingual Film if you are allergic to buprenorphine or naloxone.

### **What should I tell my healthcare provider before taking Buprenorphine and Naloxone Sublingual Film?**

Before taking Buprenorphine and Naloxone Sublingual Film, tell your doctor if you currently have or are:

- Liver or kidney problems
- Trouble breathing or lung problems
- An enlarged prostate gland (men)
- A head injury or brain problem
- Problems urinating
- A curve in your spine that affects your breathing
- Gallbladder problems
- Adrenal gland problems
- Addison's disease
- Low thyroid (hypothyroidism)
- A history of alcoholism
- Mental problems such as hallucinations (seeing or hearing things that are not there)
- Any other medical condition
- Pregnant, plan to become pregnant, or are breastfeeding.

### **Tell your healthcare provider about all medications and herbal products you take, including prescription and over-the-counter medications, vitamins and herbal supplements.**

Be especially careful about taking other medications that may make you sleepy, such as pain medications, tranquilizers, antidepressant medications, sleeping pills, anxiety medications or antihistamines.

### **What are possible side effects of Buprenorphine and Naloxone Sublingual Film?**

Respiratory problems, sleepiness, dizziness, problems with coordination, dependency or abuse, liver problems, allergic reactions, opioid withdrawal, and decrease in blood pressure.

Call a doctor or get emergency help right away if you:

- Feel sleepy and uncoordinated
- Have blurred vision
- Have slurred speech
- Cannot think well or clearly
- Have slowed reflexes and breathing

### **The most common side effects of Buprenorphine and Naloxone Sublingual Film include:**

- Nausea
- Vomiting
- Drug withdrawal syndrome
- Headache
- Sweating
- Numb mouth
- Constipation
- Swollen and/or painful tongue
- The inside of your mouth is more red than normal
- Intoxication (feeling lightheaded or drunk)
- Disturbance in attention

- Irregular heart beat (palpitations)
- Decrease in sleep (insomnia)
- Blurred vision
- Back pain
- Fainting
- Dizziness
- Sleepiness

These are not all the possible side effects of Buprenorphine and Naloxone Sublingual Film. Please refer to the Medication Guide for a complete list of possible side effects associated with Buprenorphine and Naloxone Sublingual Film.

KEEP BUPRENORPHINE AND NALOXONE SUBLINGUAL FILM 2 MG/0.5 MG, 4 MG/1 MG, 8 MG/2 MG, AND 12 MG/3 MG IN A SECURE PLACE AWAY FROM CHILDREN. ACCIDENTAL USE BY A CHILD IS A MEDICAL EMERGENCY AND CAN RESULT IN DEATH. IF A CHILD ACCIDENTALLY USES BUPRENORPHINE AND NALOXONE SUBLINGUAL FILM, GET EMERGENCY HELP RIGHT AWAY.

### **What should I avoid while taking Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg?**

- Buprenorphine can cause drowsiness and slow reaction times. Do not drive, operate heavy machinery, or perform any other physical activities until you know how this medication affects you. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take Buprenorphine and Naloxone Sublingual Film.
- You should not drink alcohol while using Buprenorphine and Naloxone Sublingual Film as this can lead to loss of consciousness or even death.

For more information, ask your healthcare provider or pharmacist. You are encouraged to report negative side effects of prescription drugs. To report suspected side effects, call Dr. Reddy's Laboratories Medical Information Hotline at 1-888-DRL-DRUG (1-888-375-3784) or via email to [medinfo@drreddys.com](mailto:medinfo@drreddys.com) or contact the USFDA at 1-800-FDA-1088 (1-800-332-1088) or online at <http://www.fda.gov/safety/medwatch>.

### **Indication and Usage**

Buprenorphine and Naloxone Sublingual Film is a prescription medication used to treat adults who are addicted to (dependent on) opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy. Buprenorphine helps suppress withdrawal symptoms caused by discontinuation of opioid drugs, and naloxone reverses and blocks the effect of opioids.

Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, is a controlled substance (CIII) because it contains buprenorphine, which can be a target for people who abuse prescription medications or street drugs. Keep your Buprenorphine and Naloxone Sublingual Film in a safe place to protect it from theft. Never give your Buprenorphine and Naloxone Sublingual Film to anyone else; it can cause death or harm them. Selling or giving away this medication is against the law.

Always take Buprenorphine and Naloxone Sublingual Film exactly as your doctor tells you. Your doctor may change your dose after seeing how it affects you. Do not change your dose unless your doctor tells you to change it.

Do not take Buprenorphine and Naloxone Sublingual Film more often than prescribed by your doctor.

Please click below for full **Prescribing Information including Medication Guide**.

[http://www.drreddys.com/pi/Buprenorphine\\_and\\_Naloxone\\_Sublingual\\_Film\\_2mg-0.5mg\\_and\\_8mg-2mg\\_Prescribing\\_Information.pdf](http://www.drreddys.com/pi/Buprenorphine_and_Naloxone_Sublingual_Film_2mg-0.5mg_and_8mg-2mg_Prescribing_Information.pdf)

[http://www.drreddys.com/pi/Buprenorphine\\_and\\_Naloxone\\_Sublingual\\_Film\\_4mg-1mg\\_and\\_12mg-3mg\\_Prescribing\\_Information.pdf](http://www.drreddys.com/pi/Buprenorphine_and_Naloxone_Sublingual_Film_4mg-1mg_and_12mg-3mg_Prescribing_Information.pdf)

Suboxone® is a registered trademark of Indivior UK Ltd.

\*IMS National Sales Perspective: Retail and Non-Retail MAT April 2018

\*\*Further information on REMS can be found at [www.btodrems.com](http://www.btodrems.com)

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**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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The company assumes no obligation to update any information contained herein.