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## Dr. Reddy's Laboratories announces the re-launch of its Buprenorphine and Naloxone Sublingual Film after favorable ruling in patent litigation

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For Immediate Release

**Hyderabad, India and Princeton, NJ, USA. February 20, 2019** - Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as "Dr. Reddy's") announced today the re-launch of its 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 re-launch comes on the heels of a favorable decision issued by the United States Court of Appeals for the Federal Circuit concluding that Indivior had not shown that it is likely to succeed on its claim that Dr. Reddy's product infringes U.S. Patent No. 9,931,305. The Federal Circuit's decision vacates the District Court's preliminary injunction that had prohibited Dr. Reddy's from selling its generic version of Suboxone® (buprenorphine and naloxone) sublingual film. The Federal Circuit's decision went into effective yesterday. As a result of the Federal Circuit's ruling, Dr. Reddy's has resumed shipping of the product.

"We are pleased with the decision of the appellate court in Dr. Reddy's favor, vacating the preliminary injunction that had prevented Dr. Reddy's from continuing to market this important drug to the public," explains Marc Kikuchi, Chief Executive Officer, North America Generics. "Dr. Reddy's is committed to providing affordable treatment options for opioid use disorder and addiction. We look forward to helping patients and our communities in the United States who are impacted by the opioid epidemic."

In June 2018, the U.S. Food and Drug Administration (USFDA) approved Dr. Reddy's Buprenorphine and Naloxone Sublingual Film, in four strengths including 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, for sale in the U.S. market. The product was launched immediately after approval, with sales and commercialization activities halted as a result of a court-imposed temporary restraining order (TRO) and preliminary injunction against Dr. Reddy's. The TRO and preliminary injunction did not prohibit commercial manufacturing of the product.

**Important Safety Information:** Buprenorphine and Naloxone Sublingual Film, 2mg/0.5mg, 4mg/1mg, 8mg/2mg, and 12mg/3mg

**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?**

- Keep buprenorphine and naloxone sublingual film 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.
- 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.
- Do not switch from Buprenorphine and Naloxone Sublingual Film to other medicines that contain buprenorphine without talking with your doctor.
- 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 occur 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, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg?**

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, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg?**

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

- Liver or kidney disease
- Trouble breathing or lung disease
- An enlarged prostate gland (men)
- A head injury or brain complication
- Problems urinating
- A curve in your spine that affects your breathing
- Gallbladder complications
- Adrenal gland complications
- Addison's disease
- Low thyroid (hypothyroidism)
- A history of alcoholism
- Mental issues 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, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg?**

- Respiratory problems
- Sleepiness, dizziness, problems with coordination
- Dependency or abuse
- Liver problems
- Allergic reaction
- Opioid withdrawal
- 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, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg:**

- 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.

**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?**

- Do not drive, operate heavy machinery, or perform any other physical activities until you know how this medication affects you. Buprenorphine can cause drowsiness and slow reaction times. 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 Call Center 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.

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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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