

June 1, 2023

✓ **BSE Limited**

Department of Corporate Services,  
P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
**MUMBAI - 400 001.**

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**MUMBAI - 400 051.**

**Dear Sir/Madam,**

**Sub: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').**

We are pleased to enclose a Press Release as regards, receipt of U.S. FDA approval for the Company's Abbreviated New Drug Application, Diazepam Rectal Gel, 10 mg and 20 mg, Rectal Delivery System, a generic equivalent of Diastat® AcuDial™ Rectal Delivery System, 10 mg and 20 mg, of Bausch Health US, LLC.

This may kindly considered as a disclosure pursuant to Regulation 30 of SEBI Listing Regulations.

The above is for your information and dissemination.

Thanking you,

**FOR LUPIN LIMITED**

**R. V. SATAM**  
**COMPANY SECRETARY**  
**(ACS-11973)**

**Encl: - a/a**



**LUPIN**



BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

## Lupin Receives Approval from U.S. FDA for Diazepam Rectal Gel

**Mumbai, Baltimore, June 01, 2023:** Global pharma major Lupin Limited (Lupin) today announced that its wholly-owned subsidiary, Novel Laboratories Inc., based in Somerset, New Jersey, has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Diazepam Rectal Gel, 10 mg and 20 mg, Rectal Delivery System, a generic equivalent of Diastat® AcuDial™ Rectal Delivery System, 10 mg and 20 mg, of Bausch Health US, LLC.

Diazepam Rectal Gel (RLD Diastat® AcuDial™) had estimated annual sales of USD 34 million in the U.S. (IQVIA MAT Mar 2023).

### About Lupin

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

The Company enjoys a leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has a significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS), and women's health areas. Lupin is the third-largest pharmaceutical company in the U.S. by prescriptions. The company invested 7.9% of its revenue in research and development in FY23.

Lupin has 15 manufacturing sites, 7 research centers, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

Please visit [www.lupin.com](http://www.lupin.com) for more information.

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Twitter: <https://twitter.com/LupinGlobal> | LinkedIn: <https://www.linkedin.com/company/lupin>

Facebook: <http://www.facebook.com/LupinWorld/>

**For further information or queries please contact –**

### Shweta Munjal

Vice President & Global Head – Corporate Communications

Email: [shwetamunjal@lupin.com](mailto:shwetamunjal@lupin.com)

### \*Safe Harbor Statement

Diastat® AcuDial™ are registered trademarks of Bausch Health Companies Inc.