

14th October, 2024

BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai - 400 001. Script Code: 500259	The National Stock Exchange of India Limited Exchange Plaza, 5 th Floor Plot No. C/1, G. Block Bandra Kurla Complex, Bandra (East), Mumbai – 400 051. Script Code: LYKALABS
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Dear Sir/s

Sub.: Intimation under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the LODR)

Ref.: Receipt of product permission from Central Drugs Standard Control Organization of India Pregabalin Gel 8% w/w

Pursuant to the Regulation 30 of the LODR, we would like to inform you that, the Company has received the product permission from the Central Drugs Standard Control Organization of India to Manufacture and Market Pregabalin Gel 8% w/w in India.

A copy of the press release issued by the Company in this regard is enclosed herewith.

Kindly take the above information on your record.

Thanking you.

Yours faithfully
For **Lyka Labs Limited**

Kunal Gandhi
Managing Director

DIN: 01516156

Encl.: as above

October 14, 2024

Lyka's Patent Pending Drug **Pregabalin Gel 8% w/w** for the Treatment of **Diabetic Neuropathic Pain** receives approval from CDSCO

India is considered to be amongst the top 2 countries in the world with a rising number of diabetes patients. Over a period of time, almost 50% of patients with diabetes develop symptoms such as burning pain, prickling pain, tingling, electric shock-like feeling, aching, tightness or extreme sensitivity to light touch. This is called Diabetic Neuropathic Pain.

The most effective way to treat Diabetic Neuropathic Pain is a comprehensive approach and patients are often prescribed specific oral pain killers such as Pregabalin Capsules, which have been available in the Indian Market for over 2 decades. Pregabalin Capsules are known to cause side effects. One approach to overcome side effects of oral drugs used for pain relief is to use their topical applications such as gel, ointments, or creams.

Lyka has developed a novel patent pending topical gel formulation of Pregabalin. After extensive research and successfully completion of the Phase III Clinical Trials, Lyka has received the CDSCO approval for manufacturing and marketing of Pregabalin Gel 8% w/w for the use in patients with Diabetic Neuropathic Pain.

In the Indian study, 210 patients were divided into two treatment groups. One group was treated with topical Pregabalin Gel while the other group was treated with oral Pregabalin Capsules, for a period of 63 days. On completion of the study, it showed that topical Pregabalin Gel was well tolerated by the patients and was equally effective as oral Pregabalin Capsules in relieving pain. The side effects were significantly lower in topical Pregabalin Gel in comparison to oral Pregabalin Capsules. Majority patients reported significant relief from pain after the use of topical Pregabalin Gel. The doctors who studied these patients were satisfied with the effectiveness and safety of topical Pregabalin Gel 8% w/w for the use in Diabetic Neuropathic Pain.

About Lyka Labs Limited

Lyka is a pharmaceutical company with strong capabilities in Sterile and Topical Preparations. From its R&D Centre in Mumbai, Lyka is currently working on development of a wide range of New Formulations and New Drug Delivery Systems in its focus areas of Lyophilized Injectables and Topical Preparations.

For more Information:

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