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NSE: LUPIN

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NEW

Now Available!

Generic Duloxetine 40 mg Delayed- Release (DR) Capsules

- The **FIRST & ONLY** Generic 40 mg Duloxetine DR Capsule formulation on the market
- Adds to the available dosing options for greater flexibility of treatment
- Same active ingredient as Cymbalta® (duloxetine delayed-release capsules)

Prescribe Generic
Duloxetine 40mg DR
Capsules Today



www.lupinpharmaceuticals.com

Cymbalta® is a registered trademark of Eli Lilly and Co.

Lupin launches first ever Duloxetine 40mg Delayed-Release Capsules in the US

Mumbai & Baltimore, September 03, 2015: Pharma major Lupin Limited announced today that its subsidiary Lupin Pharmaceuticals, Inc. (Lupin) has launched its Duloxetine 40 mg Delayed-Release (DR) Capsule, which is the first and only generic Duloxetine formulation to become available in 40 mg dosage strength. Lupin is excited to bring this new strength to market, as it adds to the currently-available dosing options for greater flexibility of treatment.

Lupin is the only generic manufacturer to offer all Duloxetine dosage strengths – the 20 mg, 30 mg, 60 mg, and now the newest 40 mg. Lupin's generic Duloxetine 40 mg DR capsules are therefore the first and only capsule available for patients in this dosage strength.

Cymbalta® Delayed-Release Capsules 20 mg, 30 mg and 60 mg strengths had annual U.S sales of approximately USD 1.05 billion (Brand + Generics - IMS MAT June 2015).

Please see the Important Safety Information including a Black Box Warning below. Full prescribing information is available at <http://www.dulox40mgpi.com/pi.pdf>.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

- **Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.**
- **Monitor for worsening and emergence of suicidal thoughts and behaviors.**

INDICATIONS:

Duloxetine delayed-release (DR) capsules USP are a prescription medication used to treat or manage:

- Major Depressive Disorder
- Generalized Anxiety Disorder
- Diabetic Peripheral Neuropathic Pain
- Chronic Musculoskeletal Pain



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SELECT IMPORTANT SAFETY INFORMATION

Patients should NOT take Duloxetine if:

- They are currently on or have stopped treatment with a monoamine oxidase inhibitor (MAOI) within the last 14 days. Patients should not be treated with an MAOI within 5 days of stopping treatment with duloxetine, as this could cause serious or life-threatening side effects
- They are currently being treated with linezolid or intravenous methylene blue
- They are currently being treated with inhibitors of CYP1A2 or thioridazine.

SELECT ADDITIONAL WARNINGS & PRECAUTIONS:

Avoid use in patients with chronic liver disease or cirrhosis as hepatic failure, sometimes fatal, has been reported in patients treated with duloxetine. Duloxetine should be discontinued in patients who develop right, upper abdominal pain, jaundice or other evidence of clinically significant liver dysfunction. Duloxetine should be avoided in patients with severe renal impairment, and should not be prescribed to patients with substantial alcohol use.

Cases of orthostatic hypotension, falls and syncope have been reported with duloxetine therapy.

Serotonin Syndrome has been reported with SSRIs and SNRIs, including with duloxetine, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone and St. John's Wort). Patients should be monitored for the emergence of Serotonin Syndrome and if symptoms occur, discontinue duloxetine and initiate supportive treatment.

Duloxetine may increase the risk of bleeding events. Patients should be cautioned about the risk of bleeding associated with the concomitant use of duloxetine and NSAIDs, aspirin, or other drugs that affect coagulation.

Severe skin reactions can occur with duloxetine. Duloxetine should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions or any other sign of hypersensitivity if no other etiology can be identified.

Discontinuation of duloxetine may result in symptoms, including dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue.

Activation of mania or hypomania has occurred in patients treated with duloxetine.



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Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with anti-depressants.

Duloxetine should be prescribed with care in patients with a history of seizure disorder, and blood pressure should be monitored prior to initiating treatment and periodically throughout treatment.

Cases of hyponatremia have been reported in patients treated with duloxetine.

Duloxetine may worsen glucose control in diabetes. In diabetic peripheral neuropathic pain patients, small increases in fasting blood glucose, and HbA have been observed.

The most common adverse reactions include: dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

Duloxetine may cause fetal harm, so talk to your patients if they are or plan to become pregnant. Caution should be exercised when duloxetine is administered to nursing mothers.

About Lupin Limited

Headquartered in Mumbai, Lupin is an innovation led transnational pharmaceutical company producing and developing a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership positions in the Anti-TB and Cephalosporin segment.

Lupin is the 6th largest and fastest growing top 10 generics player in the US (5.5% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales globally. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan (ranked 8th) and South Africa (ranked 4th – IMS Health).

For the financial year ended 31st March 2015, Lupin's Consolidated turnover and Profit after Tax were Rs. 125,997 million (USD 2.06 billion) and Rs. 24,032 million (USD 393 million) respectively. Please visit <http://www.lupin.com> for more information.

About Lupin Pharmaceuticals Inc.

Headquartered in Baltimore, Maryland, Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, affordable generic medicines and branded formulations trusted by healthcare professionals and patients across geographies. For more information, please do visit <http://www.lupinpharmaceuticals.com>

You could also follow us on **Twitter** – www.twitter.com/lupinlimited

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