Endo Launches Dexlansoprazole Capsules, Generic Version of Dexilant®

June 15, 2023

DUBLIN, June 15, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that one of its operating companies, Par Pharmaceutical, Inc., has begun shipping dexlansoprazole 30 mg capsules, a generic version of Takeda's Dexilant®. This additional dosage strength rounds out the product family, now with both 30 mg and 60 mg delayed-release capsules.

"We're proud to provide this high-quality, affordable generic medication to appropriate patients," said Scott Sims, Senior Vice President and General Manager, Injectable Solutions & Generics at Endo. "The dexlansoprazole product family strengthens our portfolio and our reputation as a reliable supplier."

Dexlansoprazole is a proton pump inhibitor with a novel delivery system approved for the treatment of erosive esophagitis and heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).

According to IQVIA ™, Dexilant® 30 mg sales were approximately $45 million for the 12 months ended April 30, 2023.

Dexilant® is a registered trademark of Takeda Pharmaceuticals U.S.A., Inc.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Dexlansoprazole delayed-release capsules are contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute tubulointerstitial nephritis and urticaria.
- PPIs, including dexlansoprazole delayed-release capsules, are contraindicated with rilpivirine-containing products.

WARNINGS AND PRECAUTIONS

Dexlansoprazole Delayed-Release Capsules, 60 mg, contain FD&C Yellow #5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow #5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Presence of Gastric Malignancy: In adults, symptomatic response to therapy with dexlansoprazole does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with a PPI. In older patients, also consider an endoscopy.

Acute Tubulointerstitial Nephritis (TIN): TIN has been observed in patients taking PPIs and may occur at any point during PPI therapy. Patients may present with varying signs and symptoms, from symptomatic hypersensitivity reactions to non-specific symptoms of decreased renal function (eg, malaise, nausea, anorexia). Discontinue dexlansoprazole and evaluate patients with suspected acute TIN.

Clostridium difficile-Associated Diarrhea: Published observational studies suggest that PPI therapy like dexlansoprazole may be associated with an increased risk of Clostridium difficile-associated diarrhea, especially in hospitalized patients. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.

Bone Fracture: Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the conditions being treated.

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported in association with the use of PPIs. Discontinue dexlansoprazole delayed-release capsules at the first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity and consider further evaluation.

Cutaneous and Systemic Lupus Erythematosus (CLE and SLE): CLE and SLE have been reported in patients taking PPIs. These events have occurred as both new onset and an exacerbation of existing autoimmune disease. The majority of PPI-induced lupus erythematosus cases were CLE. The most common form of CLE reported in patients treated with PPIs was subacute CLE (SCLE) and occurred within weeks to years after continuous drug therapy in patients ranging from infants to the elderly. SLE is less commonly reported than CLE in patients receiving PPIs. Onset of SLE typically occurred within days to years after initiating treatment primarily in patients ranging from young adults to the elderly. The majority of patients presented with rash; however, arthralgia and cytopenia were also reported. Avoid administration of PPIs for longer than medically indicated. If signs or symptoms consistent with CLE or SLE are noted in patients receiving dexlansoprazole delayed-release capsules, discontinue the drug and refer the patient to the appropriate specialist for evaluation.

Cyanocobalamin (Vitamin B12) Deficiency: Daily treatment with any acid-suppressing medications over a long period of time (eg, longer than three years) may lead to malabsorption of cyanocobalamin (Vitamin B12) caused by hypo- or achlorhydria. Rare reports of cyanocobalamin deficiency occurring with acid-suppressing therapy have been reported in the literature.

Hypomagnesemia and Mineral Metabolism: Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. Hypomagnesemia may lead to hypocalcemia and/or hypokalemia and may exacerbate underlying hypocalcemia in at-risk patients. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the PPI. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (eg, diuretics), health care professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.

Interactions with Investigations for Neuroendocrine Tumors: Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors. Healthcare providers should temporarily stop dexlansoprazole treatment at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high.

Interaction with Methotrexate: Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.

Fundic Gland Polyps: PPI use is associated with an increased risk of fundic gland polyps that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

Risk of Heart Valve Thickening in Pediatric Patients Less Than Two Years of Age: Dexlansoprazole is not recommended in pediatric patients less than two years of age.

ADVERSE REACTIONS

- Adults (≥2%): diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence.
- Patients 12 to 17 years of age (≥5%): headache, abdominal pain, diarrhea, nasopharyngitis, and oropharyngeal pain.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause adverse effects on fetal bone growth and development.

Pediatrics: Based on data with lansoprazole, dexlansoprazole is not effective in patients with symptomatic GERD 1 month to less than 1 year of age and nonclinical studies have demonstrated adverse effects in juvenile rats.

INDICATIONS AND USAGE

Healing of Erosive Esophagitis (EE): Dexlansoprazole delayed-release capsules are indicated in patients 12 years of age and older for healing of all grades of EE for up to eight weeks.

Maintenance of Healed Erosive Esophagitis and Relief of Heartburn: Dexlansoprazole delayed-release capsules are indicated in patients 12 years of age and older to maintain healing of EE and relief of heartburn for up to six months in adults and 16 weeks in patients 12 to 17 years of age.

Treatment of Symptomatic Non-Erosive Gastroesophageal Reflux Disease: Dexlansoprazole delayed-release capsules are indicated in patients 12 years of age and older for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for four weeks.

Please click for Full Prescribing Information.

About Endo
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation

Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Mr. Sims, any statements relating to product launch, commercialization, sales, supply or distribution, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

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