Endo Launches Colchicine Capsules, Generic Version of MITIGARE®

November 2, 2023

DUBLIN, Nov. 2, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that one of its operating companies, Par Pharmaceutical, Inc., has begun shipping colchicine 0.6 mg capsules, a generic version of Hikma's MITIGARE®. This is the first generic colchicine capsule approved by the U.S. Food and Drug Administration.

"We are pleased to offer this high-quality, affordable medication," said Scott Sims, Senior Vice President and General Manager, Injectable Solutions & Generics at Endo. "As a reliable supplier of generic products, we take pride in providing choices to appropriate patients."

Colchicine capsules are indicated for prophylaxis of gout flares in adults.

According to IQVIA ™, colchicine capsules sales were approximately $65.4 million for the 12 months ended September 30, 2023.

MITIGARE® is a registered trademark of Hikma Pharmaceuticals USA, Inc.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Patients with renal or hepatic impairment should not be given colchicine with drugs that inhibit both P-glycoprotein and CYP3A4 inhibitors. Combining these dual inhibitors with colchicine in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity.
Patients with both renal and hepatic impairment should not be given colchicine.

WARNINGS AND PRECAUTIONS
Fatal Overdose: Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. Colchicine should be kept out of the reach of children.
Blood Dyscrasias: Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses.
Interactions with CYP3A4 and P-gp Inhibitors: Coadministration of colchicine with dual P-gp and CYP3A4 inhibitors has resulted in life-threatening interactions and death.
Neuromuscular Toxicity: Neuromuscular toxicity and rhabdomyolysis have been reported from chronic treatment with colchicine in therapeutic doses, especially in combination with other drugs known to cause this effect. Patients with impaired renal function and elderly patients (even those with normal renal and hepatic function) are at increased risk. Consider temporary interruption or discontinuation of colchicine.

ADVERSE REACTIONS
The most commonly reported adverse reactions with colchicine are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.

DRUG INTERACTIONS

- Coadministration of P-gp or CYP3A4 inhibitors or inhibitors of both P-gp and CYP3A4 (e.g., clarithromycin or cyclosporine) have been reported to lead to colchicine toxicity. The potential for drug-drug interactions must be considered prior to and during therapy.
- Concomitant use of colchicine and inhibitors of CYP3A4 or P-gp should be avoided if possible. If coadministration of colchicine and an inhibitor of CYP3A4 or P-gp is necessary, the dose of colchicine should be reduced and the patient should be monitored carefully for colchicine toxicity

USE IN SPECIFIC POPULATIONS

- In the presence of renal or hepatic impairment, patients should be monitored closely and dose adjustment should be considered as necessary.
- Pregnancy: Use only if the potential benefit justifies the potential risk to the fetus (8.1).
- Nursing Mothers: Caution should be exercised when administered to a nursing woman (8.3).
- Geriatric Use: The recommended dose of colchicine should be based on renal/hepatic function (8.5).

INDICATION AND USAGE
Colchicine Capsules are indicated for prophylaxis of gout flares in adults.
Limitations of use: The safety and effectiveness of colchicine for acute treatment of gout flares during prophylaxis has not been studied.

Colchicine is not an analgesic medication and should not be used to treat pain from other causes.

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, shipping, quality, affordability, reliability or sales, 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.

SOURCE Endo International plc