hikma.

Press Release

Hikma launches Methylergonovine Maleate Tablets, USP

London, 30 May 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) announces that its wholly-owned US subsidiary, West-Ward Pharmaceuticals Corp. (West-Ward), has launched Methylergonovine Maleate Tablets, USP, 0.2mg, the generic equivalent to Methergine®.[1]

Methylergonovine Maleate Tablets are a semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage.

West-Ward has partnered with Granules Pharmaceuticals Inc. (Granules) to launch Methylergonovine Maleate Tablets. Under the terms of the agreement, Hikma has the exclusive rights to distribute and market Granules' Methylergonovine Maleate Tablets in the US market.

According to IQVIA, US sales of Methylergonovine Maleate Tablets, USP, 0.2mg were approximately $70 million in the 12 months ending March 2018.

Brian Hoffmann, President, Generics Division, said, "We are very pleased to be entering into a partnership with Granules, adding this important oxytocic agent to our product portfolio in the US. This partnership demonstrates our focus on improving patient's access to high-quality, affordable medicines."

"This is the first product we have commercialized from our manufacturing facility in the Chantilly, VA and we are happy to have collaborated with West-Ward. The launch of generic Methergine tablets, the first generic in the market plays into our strategy of identifying patient needs and catering to them with economical alternatives." said Ms. Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals Inc.

Important Safety Information

Methergine tablets are contraindicated for patients with the following conditions: hypertension, toxemia, pregnancy, and hypersensitivity.

General
This drug should not be administered I.V. routinely because of the possibility of inducing sudden hypertensive and cerebrovascular accidents. If I.V administration is considered essential as a lifesaving measure, methylergonovine maleate should be given slowly over a period of no less than 60 seconds with careful monitoring of blood pressure. Intra-arterial or periarterial injection should be strictly avoided. Caution should be exercised in presence of impaired hepatic or renal function.

Breast-Feeding
Mothers should not breast-feed during treatment with methylergonovine maleate. Milk secreted during this period should be discarded. Methylergonovine maleate may produce adverse effects in the breast-feeding infant. Methylergonovine maleate may also reduce the yield of breast milk. Mothers should wait at least 12 hours after administration of the last dose of methylergonovine maleate before initiating or resuming breast feeding.

Coronary Artery Disease

[1] Methergine® is a registered trademark of Lupin.

Patients with coronary artery disease or risk factors for coronary artery disease (e.g., smoking, obesity, diabetes, high cholesterol) may be more susceptible to developing myocardial ischemia and infarction associated with methylergonovine-induced vasospasm.

Medication Errors
Inadvertent administration of methylergonovine maleate to newborn infants has been reported. In these cases of inadvertent neonatal exposure, symptoms such as respiratory depression, convulsions, cyanosis and oliguria have been reported. Usual treatment is symptomatic. However, in severe cases, respiratory and cardiovascular support is required. Methylergonovine maleate has been administered instead of vitamin K and Hepatitis B vaccine, medications which are routinely administered to the newborn. Due to the potential for accidental neonatal exposure, methylergonovine maleate injection should be stored separately from medications intended for neonatal administration.

PRECAUTIONS

General
Caution should be exercised in the presence of sepsis, obliterative vascular disease. Also use with caution during the second stage of labor. The necessity for manual removal of a retained placenta should occur only rarely with proper technique and adequate allowance of time for its spontaneous separation.

Drug Interactions
There have been rare reports of serious adverse events in connection with the co-administration of certain ergot alkaloid drugs (e.g., dihydroergotamine and ergotamine) and potent CYP3A4 inhibitors, resulting in vasospasm leading to cerebral ischemia and/or ischemia of the extremities. Although there have been no reports of such interactions with methylergonovine alone, potent CYP3A4 inhibitors should not be co-administered with methylergonovine.

Caution should be exercised when methylergonovine maleate is used concurrently with beta-blockers. Concomitant administration with beta-blockers may enhance the vasoconstrictive action of ergot alkaloids.

Caution should be exercised when methylergonovine maleate is used concurrently with other vasoconstrictors, ergot alkaloids, or prostaglandins.

Use of methylergonovine maleate is contraindicated during pregnancy because of its uterotonic effects.

Safety and effectiveness in pediatric patients have not been established.

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About Hikma

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We're a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner in the MENA region, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit www.hikma.com.

About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India is a growing pharmaceutical manufacturing company with best in class facilities and is committed to operational excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules India support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. For more information, please visit www.granulesindia.com.