
Hikma launches Palonosetron Hydrochloride Injection

London, 29 March 2018 – Hikma Pharmaceuticals PLC (Hikma) (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 Palonosetron Hydrochloride (HCl) Injection, 0.25mg/2mL.

West-Ward's Palonosetron HCl Injection is a serotonin-3 (5-HT₃) receptor antagonist indicated in adults for:

- Moderately emetogenic cancer chemotherapy – prevention of acute and delayed nausea and vomiting associated with initial and repeat courses
- Highly emetogenic cancer chemotherapy – prevention of acute nausea and vomiting associated with initial and repeat courses

According to IQVIA, US sales of Palonosetron HCl Injection were approximately \$447 million in the 12 months ending January 2018.

Riad Mechlaoui, Chief Executive Officer, Injectables Division, said, "We are very pleased to add Palonosetron HCl Injection to our oncology portfolio. The launch of this product further expands our broad Injectables portfolio, bringing value to our customers and patients in the US hospital setting, as well as driving long-term, sustainable growth for our business."

Important Safety Information

WARNINGS AND PRECAUTIONS

The following warnings and precautions should be taken when administering Palonosetron Hydrochloride Injection:

- Hypersensitivity reactions, including anaphylaxis, have been reported with or without known hypersensitivity to other 5-HT₃ receptor antagonists.
- Serotonin syndrome has been reported with 5-HT₃ receptor antagonists. Signs and symptoms include: mental status change, autonomic instability, neuromuscular symptoms, and seizures, with or without gastrointestinal symptoms. Inform patient of the increased risk.

Palonosetron HCl Injection is contraindicated in patients known to have hypersensitivity to the drug or any of its components.

In clinical trials of palonosetron hydrochloride, the most common adverse reactions were headache, constipation, diarrhea, and dizziness.



Infrequent adverse reactions include, hypertension, myocardial ischemia, rash, hearing and vision irritation, diarrhea, dry mouth, fatigue, flu-like syndrome, asymptomatic increases in AST and/or ALT and bilirubin, hyperglycemia, anorexia, arthralgia, dizziness, insomnia, anxiety, urinary retention and vein discoloration.

Very rare cases of hypersensitivity reactions including anaphylaxis and anaphylactic shock and injection site reactions, including burning, induration, discomfort and pain, have been reported from post approval use.

Patient Counselling Information should be shared with the patient prior to administration. Patients should be advised to read the FDA-approved Patient Information.

Please refer to the Package Insert for full prescribing information, available [here](#). Additional information on West-Ward products is available at www.west-ward.com.

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About Hikma

Hikma helps puts 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.