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Press Release

Hikma launches prefilled syringes in the US

Heparin Sodium Injection in a ready-to-administer syringe is the first product using Hikma's new injectable manufacturing capability

London, 17 September 2019 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P) the multinational pharmaceutical company, has launched a new prefilled syringe capability in the US through its affiliate, Hikma Pharmaceuticals USA Inc.[1] The first Hikma medicine available in prefilled syringe form is Heparin Sodium Injection, USP, 5000 Units/mL.

"Medical professionals are always in need of tools that help them improve the speed, safety and accuracy of patient care and that is why Hikma is excited to launch our prefilled syringe capability," said Dan Motto, Hikma's EVP of Commercial & Business Development, US Injectables. "Our Heparin Sodium Injection prefilled syringes are ready-to-administer and will help hospitals, pharmacists, doctors and nurses treat patients faster, more easily and with reduced risk. This is another example of how Hikma is using its capabilities as a leading generic pharmaceutical company to serve the growing needs of US medical professionals and their patients."

"Hikma is continuously expanding its broad and deep portfolio of essential injectable medicines" said Riad Mishlawi, President, Hikma Injectables. "We have made significant investments in our US manufacturing capabilities to bring this new prefilled syringe capability to market, and Heparin is the first of many important medicines we will deliver in this form."

Heparin Sodium Injection is indicated for:

- Prophylaxis and treatment of venous thrombosis and pulmonary embolism;
- Prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease;
- Atrial fibrillation with embolization;
- Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation);
- Prevention of clotting in arterial and cardiac surgery;
- Prophylaxis and treatment of peripheral arterial embolism;
- Anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures

Hikma is the third largest US supplier of generic injectable medicines by volume, with a growing portfolio of over 100 products. Today one in every six injectable generic medicines used in US hospitals is a Hikma product.

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[1] Hikma Pharmaceuticals USA Inc. was formerly known as West-Ward Pharmaceuticals Corp.

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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 more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, 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 8,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, 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.

Important Safety Information for Heparin Sodium Injection, USP, 5000 Units/mL:

CONTRAINDICATIONS

The use of Heparin Sodium Injection is contraindicated in patients with the following conditions:

- History of heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis;
- Known hypersensitivity to heparin or pork products (e.g., anaphylactoid reactions).
- In whom suitable blood coagulation tests, e.g., the whole blood clotting time, partial thromboplastin time, etc., cannot be performed at appropriate intervals (this contraindication refers to full-dose heparin; there is usually no need to monitor coagulation parameters in patients receiving low-dose heparin);
- An uncontrolled active bleeding state, except when this is due to disseminated intravascular coagulation.

WARNINGS & PRECAUTIONS

The following warnings and precautions should be taken when administering Heparin Sodium Injection, USP:

- Do not use Heparin Sodium Injection as a "catheter lock flush" product. Fatal hemorrhages have occurred in pediatric patients due to medication errors in which 1 mL Heparin Sodium Injection vials were confused with 1 mL "catheter lock flush" vials.
- Avoid using heparin in the presence of major bleeding, except when the benefits of heparin therapy outweigh the potential risks.
- Hemorrhage can occur at virtually any site in patients receiving heparin. Fatal hemorrhages have occurred. Use heparin sodium with caution in disease states in which there is increased risk of hemorrhage.
- Heparin-induced thrombocytopenia (HIT) is a serious antibody-mediated reaction. HIT may progress to the development of venous and arterial thromboses, a condition referred to as heparin-induced thrombocytopenia with thrombosis (HITT). Thrombotic events may also be the initial presentation for HITT. These serious thromboembolic events include deep vein thrombosis, pulmonary embolism, cerebral vein thrombosis, limb ischemia, stroke, myocardial infarction, mesenteric thrombosis, renal arterial thrombosis, skin necrosis, gangrene of the extremities that may lead to amputation, and possibly death. HIT or HITT can occur up to several weeks after the discontinuation of heparin therapy.
- Thrombocytopenia in patients receiving heparin has been reported at frequencies up to 30%. It can occur 2 to 20 days (average 5 to 9) following the onset of heparin therapy. Monitor thrombocytopenia of any degree closely.
- When using a full dose heparin regimen, adjust the heparin dose based on frequent blood coagulation tests. If the coagulation test is unduly prolonged or if hemorrhage occurs, discontinue heparin promptly. Periodic platelet counts and hematocrits are recommended during the entire course of heparin therapy, regardless of the route of administration.
- Resistance to heparin is frequently encountered in fever, thrombosis, thrombophlebitis, infections with thrombosing tendencies, myocardial infarction, cancer, in postsurgical patients, and patients with antithrombin III deficiency.

- Patients with documented hypersensitivity to heparin should be given the drug only in clearly life-threatening situations. Because Heparin Sodium Injection is derived from animal tissue, it should be used with caution in patients with a history of allergy.

ADVERSE REACTIONS

The following adverse reactions have been reported: hemorrhage, heparin-induced thrombocytopenia (HIT) and heparin-induced thrombocytopenia and thrombosis (HITT), thrombocytopenia, heparin resistance, and hypersensitivy.

The following postmarketing adverse reactions have been reported: hemorrhage, heparin-induced thrombocytopenia (HIT) and heparin-induced thrombocytopenia and thrombosis (HITT) including delayed onset cases, local irritation (erythema, mild pain, hematoma or ulceration may follow deep subcutaneous (intrafat) injection), histamine-like reactions (site of injection or necrosis of skin during subcutaneous injection), hypersensitivity (chills, fever, urticaria, asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid reactions including shock, itching and burning, especially on the plantar side of the feet), significant elevations of aminotransferases (aspartate aminotransferase (AST) and alanine aminotransferase (ALT)), osteoporosis following long-term administration of high doses of heparin, cutaneous necrosis after systemic administration, suppression of aldosterone synthesis, delayed transient alopecia, priapism, and rebound hyperlipemia on discontinuation of heparin.

Patient Counseling Information should be shared with the patient prior to administration.
For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **http://www.fda.gov/medwatch** or call 1-800-FDA-1088.

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