

Hikma launches Norepinephrine Bitartrate Injection, USP

London, 22 March 2019 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable), the multinational pharmaceutical company, has launched Norepinephrine Bitartrate Injection, USP, 4mg/4mL in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.¹

Hikma's Norepinephrine Bitartrate Injection, USP is indicated for blood pressure control in certain acute hypotensive states (e.g., pheochromocytectomy, sympathectomy, poliomyelitis, spinal anesthesia, myocardial infarction, septicemia, blood transfusion, and drug reactions) and as an adjunct in the treatment of cardiac arrest and profound hypotension.

According to IQVIA, US sales of Norepinephrine Bitartrate Injection were approximately \$97 million in the 12 months ending January 2019.

Riad Mechlaoui, President of Injectables said, "The launch of Norepinephrine Bitartrate Injection in the US is the latest example of how Hikma is continuing to expand its comprehensive portfolio of quality injectable medicines available to US hospitals. We are committed to providing quality medicines to doctors and their patients and intend to continue identifying and launching injectable medicines that meet the growing needs of US hospitals and clinics."

Hikma is the third largest US supplier of generic injectable medicines with a growing portfolio of around 100 products. Today, one in every six injectable 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.



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 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.

Important Safety Information for Norepinephrine Bitartrate Injection, USP, 4mg/4mL:

WARNINGS AND PRECAUTIONS

Norepinephrine should not be given to patients who are hypotensive from blood volume deficits except as an emergency measure to maintain coronary and cerebral artery perfusion until blood volume replacement therapy can be completed. If norepinephrine is continuously administered to maintain blood pressure in the absence of blood volume replacement, the following may occur: severe peripheral and visceral vasoconstriction, decreased renal perfusion and urine output, poor systemic blood flow despite "normal" blood pressure, tissue hypoxia, and lactate acidosis.

Norepinephrine should also not be given to patients with mesenteric or peripheral vascular thrombosis (because of the risk of increasing ischemia and extending the area of infarction) unless, in the opinion of the attending physician, the administration of norepinephrine is necessary as a life-saving procedure.

Cyclopropane and halothane anesthetics increase cardiac autonomic irritability and therefore seem to sensitize the myocardium to the action of intravenously administered epinephrine or norepinephrine. Hence, the use of norepinephrine during cyclopropane and halothane anesthesia is generally considered contraindicated because of the risk of producing ventricular tachycardia or fibrillation.

The same type of cardiac arrhythmias may result from the use of norepinephrine in patients with profound hypoxia or hypercarbia.

The following additional warnings and precautions should be taken when administering Norepinephrine Bitartrate Injection, USP:

- Use with extreme caution in patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types.
- Norepinephrine bitartrate injection contains sodium metabisulfite, a sulfite that may cause allergic type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.
- Possibility exists that dangerously high blood pressure may be produced with overdoses of this pressor agent. The rate of flow must be watched constantly, and the patient should never be left unattended while receiving norepinephrine.
- Norepinephrine bitartrate injection is a concentrated, potent drug which must be diluted in dextrose containing solutions prior to infusion. An infusion of norepinephrine should be given into a large vein.
- Avoid the veins of the leg in elderly patients or in those suffering from occlusive vascular diseases.
- The infusion site should be checked frequently for free flow. Care should be taken to avoid extravasation of



norepinephrine.

- Norepinephrine should be given to a pregnant woman only if clearly needed.
- Caution should be used when administered to a nursing woman.
- Dose selection for an elderly patient should be cautious.

The following adverse reactions have been reported: ischemic injury, bradycardia, arrhythmias, anxiety, headache, respiratory difficulty, and extravasation necrosis at the injection site. Prolonged administration may result in plasma volume depletion.

Overdosage may result in headache, severe hypertension, reflex bradycardia, marked increase in peripheral resistance, and decreased cardiac output.

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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