

## Hikma launches Phenylephrine Hydrochloride Injection, USP

**London, 9 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 Phenylephrine Hydrochloride Injection, USP, 5mL and 10mL pharmacy bulk package vials, in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.<sup>1</sup>

Phenylephrine Hydrochloride is an alpha-1 adrenergic receptor agonist indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anesthesia.

According to IQVIA, US sales of Phenylephrine Hydrochloride Injection, USP, 5mL and 10mL vials, were approximately \$28 million in the 12 months ending June 2019.

Dan Motto, Executive Vice President, Commercial and Development, Injectables said, "We have added Phenylephrine Hydrochloride Injection, USP 5mL and 10mL vials, to our product portfolio to address hospitals' and patients' needs for this essential medicine. We are pleased to expand our Injectable portfolio with additional Phenylephrine Injection presentations. This launch is another example of our commitment to providing hospitals and doctors with a broad portfolio of high-quality injectable medicines they need to best treat their patients."

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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### 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

<sup>1</sup> Hikma Pharmaceuticals USA Inc. was formerly known as West-Ward Pharmaceuticals Corp.

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](http://www.hikma.com).

## **Important Safety Information for Phenylephrine Hydrochloride Injection, USP, 5mL and 10mL pharmacy bulk package vials:**

### WARNINGS AND PRECAUTIONS

The following warnings and precautions should be taken when administering Phenylephrine Hydrochloride Injection, USP:

- Can precipitate angina in patients with severe arteriosclerosis or history of angina, exacerbate underlying heart failure, and increase pulmonary arterial pressure.
- Severe bradycardia and decreased cardiac output can occur.
- Risk in patients with autonomic dysfunction. Pressor response can be increased.
- Extravasation of phenylephrine can cause necrosis or sloughing of tissue.
- Oxytocic drugs potentiate the pressor effect of sympathomimetic pressor amines with the potential for hemorrhagic stroke.
- This product contains sodium metabisulfite, which may cause allergic-type reactions, including life-threatening or less severe asthmatic episodes in certain susceptible people.
- Can cause excessive peripheral and visceral vasoconstriction and ischemia to vital organs, particularly in patients with extensive peripheral vascular disease.
- Monitor renal function. Phenylephrine can increase the need for renal replacement therapy in patients with septic shock.
- Phenylephrine hydrochloride should be given to a pregnant woman only if clearly needed.
- Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.
- Consider larger dosing than usual in hepatic impaired subjects.
- Consider using lower doses in patients with end stage renal disease (ESRD).

Phenylephrine hydrochloride is contraindicated in patients with hypersensitivity to it or any of its components.

The following adverse reactions have been reported: bradycardia, AV block, ventricular extrasystoles, myocardial ischemia, nausea, vomiting, chest pain, extravasation, sulfite sensitivity, headache, nervousness, paresthesia, tremor, excitability, pulmonary edema, rales, diaphoresis, pallor, piloerection, skin blanching, skin necrosis with extravasation and hypertensive crisis.

### Drug interactions:

- The pressor effect of phenylephrine hydrochloride is increased in patients receiving agonists such as: (i) monoamine oxidase inhibitors (MAOI); (ii)  $\beta$ -adrenergic blockers; (iii)  $\alpha$ -2 adrenergic agonists; (iv) steroids; (v) steroids; (vi) norepinephrine transport inhibitors; (vii) ergot alkaloids' (viii) centrally-acting sympatholytic agents; and (ix) atropine sulfate.
- Antagonists,  $\alpha$ -adrenergic blocking agents, including phenothiazines, and amiodarone block phenylephrine and are in turn blocked by phenylephrine.



**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](http://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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