Press Release

Hikma launches Thiamine Hydrochloride Injection, USP

London, 18 February 2021 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Thiamine Hydrochloride Injection, USP, 200mg/2mL, in the US, through its US affiliate, Hikma Pharmaceuticals USA Inc.

Thiamine Hydrochloride Injection, USP is indicated for the treatment of thiamine deficiency or beriberi. It is used to treat both the dry (major symptoms related to the nervous system) or wet (major symptoms related to the cardiovascular system) variety.

According to IQVIA, US sales of Thiamine Hydrochloride Injection, USP, 200mg/2mL, were approximately $33 million in the 12 months ending November 2020.

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.

- ENDS -

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P, BBB-/stable Fitch and Ba1/stable Moody's)

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 are 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 8,600 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

hikma.

Important Safety Information for Thiamine Hydrochloride Injection, USP, 200mg/2mL:

CONTRAINDICATIONS

A history of sensitivity to thiamine or to any of the ingredients in this drug is a contraindication.

WARNINGS & PRECAUTIONS

- This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.
- Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- Serious hypersensitivity/anaphylactic reactions can occur, especially after repeated administration. Deaths have resulted from IV or IM administration of thiamine.
- Routine testing for hypersensitivity, in many cases, may not detect hypersensitivity. Nevertheless, a skin test should be performed on patients who are suspected of drug allergies or previous reactions to thiamine, and any positive responders should not receive thiamine by injection.
- If hypersensitivity to thiamine is suspected (based on history of drug allergy or occurrence of adverse reactions after thiamine administration), administer one-hundredth of the dose intradermally and observe for 30 minutes. If no reaction occurs, full dose can be given; the patient should be observed for at least 30 minutes after injection. Be prepared to treat anaphylactic reactions regardless of the precautions taken.
- Treatment of anaphylactic reactions includes maintaining a patent airway and the use of epinephrine, oxygen, vasopressors, steroids and antihistamines.
- Simple vitamin B1 deficiency is rare. Multiple vitamin deficiencies should be suspected in any case of dietary inadequacy. The patient should be advised as to proper dietary habits during treatment so that relapses will be less likely to occur with reduction in dosage or cessation of injection therapy.

ADVERSE REACTIONS

An occasional individual may develop a hypersensitivity or life-threatening anaphylactic reaction to thiamine, especially after repeated injections. Collapse and death have been reported. A feeling of warmth, pruritus, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioneurotic edema, cyanosis, pulmonary edema, and hemorrhage into the gastrointestinal tract have also been reported. Some tenderness and induration may follow IM use.

DRUG INTERACTIONS

None listed.

USE IN SPECIFIC POPULATIONS

Usage in Pregnancy
Studies in pregnant women have not shown that thiamine hydrochloride increases the risk of fetal abnormalities if administered during pregnancy. If the drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm however, thiamine hydrochloride should be used during pregnancy only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when thiamine hydrochloride is administered to a nursing mother.

DOSAGE AND ADMINISTRATION

Wernicke-Korsakoff syndrome
Usual dosage: 100 mg IV followed by 50 to 100 mg IM daily until consuming a regular, balanced diet.

Beriberi
"Wet" beriberi with myocardial failure must be treated as an emergency cardiac condition, and thiamine must be administered slowly by the IV route in this situation. In the treatment of beriberi, 10 to 20 mg of thiamine hydrochloride are given IM three times daily for as long as two weeks.

An oral therapeutic multivitamin preparation containing 5 to 10 mg thiamine, administered daily for one month, is recommended to achieve body tissue saturation. Infantile beriberi that is mild may respond to oral therapy, but if collapse occurs, doses of 25 mg may cautiously be given IV.

Poor dietary habits should be corrected, and an abundant and well-balanced dietary intake should be prescribed.

Peripheral neuritis in pregnancy - Vomiting of pregnancy (Severe)
Patients with neuritis of pregnancy in whom vomiting is severe enough to preclude adequate oral therapy should receive 5 to 10 mg of thiamine hydrochloride IM daily.

Administration of intravenous fluids, Dextrose (in patients with marginal thiamine status)
Patients with marginal thiamine status to whom dextrose is being administered should receive 100 mg thiamine hydrochloride in each of the first few liters of IV fluid to avoid precipitating heart failure.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

OVERDOSAGE

Parenteral doses of 100 to 500 mg singly have been administered without toxic effects. However, dosages exceeding 30 mg three times a day are not utilized effectively.

When the body tissues are saturated with thiamine, it is excreted in the urine as pyrimidine. As the intake of thiamine is further increased, it appears unchanged in the urine.

INDICATIONS AND USAGE

Thiamine hydrochloride injection is effective for the treatment of thiamine deficiency or beriberi. It is used to treat both dry (major symptoms related to the nervous system) or wet (major symptoms related to the cardiovascular system) variety. Thiamine hydrochloride injection should be used where rapid restoration of thiamine is necessary, as in Wernicke's encephalopathy, infantile beriberi with acute collapse, cardiovascular disease due to thiamine deficiency, or neuritis of pregnancy if vomiting is severe. It is also indicated when giving IV dextrose to individuals with marginal thiamine status to avoid precipitation of heart failure.

Thiamine hydrochloride injection is also indicated in patients with established thiamine deficiency who cannot take thiamine orally due to coexisting severe anorexia, nausea, vomiting, or malabsorption.

Thiamine hydrochloride injection is not usually indicated for conditions of decreased oral intake or decreased gastrointestinal absorption, because multiple vitamins should usually be given.

Thiamine Hydrochloride Injection, USP FDA approved indications:

- Administration of intravenous fluids, Dextrose (in patients with marginal thiamine status)
- Beriberi
- Peripheral neuritis in pregnancy - Vomiting of pregnancy (Severe)
- Thiamine deficiency; Treatment and Prophylaxis
- Wernicke-Korsakoff syndrome

ENDING INFORMATION

For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

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