



PRESS RELEASE

Hikma launches Ifosfamide Injection

London, 18 January 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (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 Ifosfamide Injection, 1g/20mL vials, the generic equivalent to Ifex®.¹

West-Ward's Ifosfamide Injection is indicated for use in combination with certain other approved antineoplastic agents for third-line chemotherapy of germ cell testicular cancer. It should be used in combination with mesna for prophylaxis of hemorrhagic cystitis.

According to IMS Health, US sales of Ifosfamide Injection, 1g/20mL vials, were approximately \$0.6 million in the 12 months ending October 2017.

Important safety information

Warning: MYELOSUPPRESSION, NEUROTOXICITY AND UROTOXICITY

Myelosuppression can be severe and lead to fatal infections. Monitor blood counts prior to and at intervals after each treatment cycle. CNS toxicities can be severe and result in encephalopathy and death. Monitor for CNS toxicity and discontinue treatment for encephalopathy. Nephrotoxicity can be severe and result in renal failure. Hemorrhagic cystitis can be severe and can be reduced by the prophylactic use of mesna.

Warnings and Precautions

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

Myelosuppression: Can be severe and lead to fatal infections. Monitor blood counts prior to and at intervals after treatment.

Neurotoxicity: Severe and fatal neurotoxicity can occur. Carefully monitor the patient for CNS toxicity and other neurotoxic effects. Discontinue therapy should encephalopathy develop.

Urotoxicity: Severe nephrotoxicity with renal failure and death can occur. Monitor for nephrotoxicity with serum and urine chemistries. Mesna should be used to reduce hemorrhagic cystitis.

Cardiotoxicity: Arrhythmias, other ECG changes, and cardiomyopathy can occur and result in death. Use with caution in patients with cardiac risk factors and in patients with preexisting cardiac disease. The risk of cardiotoxicity is dose dependent.

Pulmonary toxicity: Interstitial pneumonitis, pulmonary fibrosis, and other forms of pulmonary toxicity with fatal outcomes can occur. Monitor for signs and symptoms of pulmonary toxicity and treat as clinically indicated.

Secondary malignancies as late sequelae have occurred.

Veno-occlusive liver disease has been reported with chemotherapy that included ifosfamide.

Pregnancy: Can cause fetal harm. Women should not become pregnant and men should not father a child during therapy. Ifosfamide is excreted in breast milk. Women must not breastfeed during treatment with ifosfamide

¹ Iflex is a registered trademark of Baxter

Ifosfamide interferes with oogenesis and spermatogenesis. Amenorrhea, azoospermia, and sterility in both sexes have been reported.

Ifosfamide may interfere with normal wound healing.

Anaphylactic/anaphylactoid reactions have been reported.

Ifosfamide injection is contraindicated in patients with known hypersensitivity to administration of ifosfamide and urinary outflow obstruction.

In clinical trials of ifosfamide monotherapy, the most common adverse reactions were alopecia, nausea/vomiting, leukopenia, anemia, CNS toxicity, hematuria, and infection.

The following adverse reactions have been reported in the post-approval use of Ifosfamide injection: Infections and Infestations; Neoplasms, Benign and Malignant and Unspecified (incl. cysts and polyps); Blood and Lymphatic Disorders; Immune System and Endocrine Disorders; Metabolism and Nutrition Disorders; Psychiatric and Nervous System Disorders; Eye and Vision Disorders; Ear and Labyrinth Disorders; Cardiac and Vascular Disorders; Respiratory, Thoracic, and Mediastinal Disorders; Gastrointestinal Disorders; Hepatobiliary Disorders; Skin, Subcutaneous Tissue, Musculoskeletal and Connective Tissue Disorders; Renal and Urinary Disorders; Reproductive System and Breast Disorders; Congenital, Familial, and Genetic Disorders.

General adverse reactions and administrative site conditions may include the following: multi-organ failure, general physical deterioration, Injection/Infusion site reactions including swelling, inflammation, pain, erythema, tenderness, pruritus; chest pain, edema, mucosal inflammation, pain, pyrexia and chills.

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

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About Hikma

Hikma Pharmaceuticals PLC is a multinational pharmaceutical group focused on developing, manufacturing and marketing a broad range of both branded and non-branded generic and in-licensed products. Hikma's operations are conducted through three businesses: 'Injectables,' 'Generics' and 'Branded,' based primarily in the Middle East and North Africa (MENA) region, where it is a market leader, the United States and Europe. In 2016, Hikma achieved revenues of \$1,950 million and profit attributable to shareholders of \$155 million.