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Press Release

Hikma launches TYZAVAN™ (vancomycin injection, USP) in the US

Ready-to-use sepsis therapy marks new advancement in time-critical treatment

London, 08 December 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, today announces the launch of the first-of-its-kind, ready-to-use vancomycin premix with room-temperature stability under the brand name TYZAVAN™ (vancomycin injection, USP).[1] TYZAVAN™ is offered in pre-filled ready-to-use bags that 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 U.S. medical professionals and their patients.

TYZAVAN™ is a glycopeptide antibacterial indicated for the treatment of the following infections in adult and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved: (i) septicemia; (ii) infective endocarditis; (iii) skin and skin structure infections; (iv) bone infections; and (v) lower respiratory tract infections.

The name TYZAVAN™ stands for "time-saving vancomycin," reflecting its ready-to-use dosage form and its purpose: delivering timely, simplified treatment when every minute counts. TYZAVAN™ is the only FDA-approved vancomycin injection available for adults and pediatric patients (1 month and older) that can be stored at room temperature and used immediately eliminating the need for compounding, thawing, assembly or activation to streamline preparation and accelerate treatment.[1]

According to Sepsis Alliance, someone in the U.S. is diagnosed with sepsis every 20 seconds, and a sepsis-related death occurs every two minutes.[2] Sepsis is a leading cause of death and hospitalization, often requiring rapid antibiotic administration as a core part of treatment. Independent studies indicate that sepsis survival rate decreases by 15% after 87–113 minutes.[3]

"The approval of TYZAVAN™ underscores our team's exceptional R&D capabilities in developing innovative healthcare solutions that enhance patient care, particularly in time-sensitive situations," said Jon Kafer, Vice President of Commercial for Hikma Injectables. "TYZAVAN™, available in ready-to-use aseptically filled bags, exemplifies our commitment to rethinking essential medicines by making them faster to administer, easier to manage and available when patients need them most. Our talented and knowledgeable commercial team will drive the launch of TYZAVAN™, ensuring its successful introduction and adoption in U.S. hospitals."

TYZAVAN™ provides hospitals and healthcare providers with a practical and scalable solution for improving time to treatment and reducing preparation complexity:

- **Ready-to-use formulation** – streamlines care by eliminating on-site preparation and IV compounding, lightening the load for pharmacy and nursing teams, while reducing handling risks and minimizing medication errors
- **Seven strengths (0.5g–2g)** – supporting flexibility for fixed and weight-based dosing
- **Room-temperature stability** – shelf life of 16 months; no refrigeration needed
- **Automated dispensing cabinet compatible** – seamlessly fits into hospital workflows

[1] TYZAVAN™ (vancomycin injection, USP) Prescribing Information. Hikma Pharmaceuticals USA Inc.
[2] Source: Sepsis Alliance
[3] Carroll D, Popa A, Hejal R, et al. 1601: Evaluation of timing of first dose antibiotic administration in patients with sepsis or septic shock. Crit Care Med. 2019;47(1):776

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This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

Enquiries

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB/stable S&P and BBB/stable Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 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 North America, 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 9,500 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 TYZAVAN™ (vancomycin injection, USP):

CONTRAINDICATIONS

TYZAVAN™ is contraindicated in patients with known hypersensitivity to vancomycin.

WARNINGS & PRECAUTIONS

- **Infusion Reactions –** Hypotension, including shock and cardiac arrest, wheezing, dyspnea, urticaria or pruritus, muscular and chest pain and “vancomycin infusion reactions” which manifests as pruritus and erythema face, neck and upper body pruritus and erythema may occur with rapid TYZAVAN™ administration (e.g., over several minutes). The reactions may be more severe in pediatric patients. To reduce the risk of infusion reactions, administer TYZAVAN™ over a period of 60 minutes or greater and also prior to intravenous anesthetic agents.
- **Nephrotoxicity –** TYZAVAN™ can result in acute kidney injury (AKI), including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis. Monitor renal function in all patients.
- **Ototoxicity –** Ototoxicity may be reversible or permanent in patients receiving vancomycin. It is higher risk in older patients and patients who are receiving higher doses and manifests as tinnitus, hearing loss, dizziness or vertigo. Serial tests of auditory function may be helpful.
- **Severe Dermatologic Reactions –** such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), and linear IgA bullous dermatosis (LABD) have been reported in association with the use of vancomycin. Cutaneous signs or symptoms reported include skin rashes, mucosal lesions, and blisters. Discontinue TYZAVAN™ at the first appearance of any signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD.
- ***Clostridioides difficile*-Associated Diarrhea (CDAD) –** has been reported with use of nearly all antibacterial agents, including vancomycin and may range in severity from mild diarrhea to fatal colitis. Evaluate patients if diarrhea occurs.
- **Hemorrhagic Occlusive Retinal Vasculitis (HORV) –** including permanent loss of vision, occurred in patients

receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by these routes have not been established by adequate and well-controlled trials. Vancomycin is not indicated for the prophylaxis of endophthalmitis.

- **Neutropenia –** Reversible neutropenia has been reported in patients receiving vancomycin. Periodically monitor leukocyte count.
- **Phlebitis and Other Administration Site Reactions –** Inflammation at the injection site has been reported. Vancomycin is irritating to tissue and must be given by a secure intravenous route of administration to reduce the risk of local irritation and phlebitis. Thrombophlebitis may occur. Administration of TYZAVAN™ by intramuscular (IM), intraperitoneal, intrathecal (intralumbar or intraventricular), or intravitreal routes has not been approved and is not recommended. The safety and efficacy of vancomycin administered by these routes have not been established by adequate and well controlled trials.
- **Development of Drug-Resistant Bacteria –** Prescribing TYZAVAN™ in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The most common adverse reactions are: (i) anaphylaxis; (ii) “vancomycin infusion reactions”; (iii) acute kidney injury; (iv) hearing loss; and (v) neutropenia.

DRUG INTERACTIONS

Anesthetic Agents: Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing.

Piperacillin-Tazobactam: Studies have detected an increased incidence of acute kidney injury in patients administered concomitant piperacillin/tazobactam and vancomycin as compared to vancomycin alone. Monitor kidney functions.

Ototoxic and/or Nephrotoxic Drugs: Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs requires more frequent monitoring of renal function.

USE IN SPECIFIC POPULATIONS

Pregnancy: The available data on the use of this formulation of TYZAVAN™ (which includes the excipient NADA) in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Lactation: There are insufficient data to inform the levels of vancomycin in human milk. There are no data on the effects of vancomycin on the breastfed infant or milk production.

Pediatric Use: More severe infusion related reactions related to vancomycin administration may occur in pediatric patients. In pediatric patients, monitor vancomycin serum concentration and renal function when administering TYZAVAN™.

Geriatric Use: TYZAVAN™ is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment: Dosage adjustment of Vancomycin Injection must be made in patients with impaired renal function. Measure trough vancomycin serum concentrations to guide intravenous therapy, especially in patients with impaired renal function or fluctuating renal function.

OVERDOSAGE

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance. For current information on the management of overdosage, contact the National Poison Control Center at 1-800-222-1222 or www.poison.org.

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INDICATIONS AND USAGE

TYZAVAN™ is a glycopeptide antibacterial indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved for the treatment of the following infections:

- Septicemia
- Infective Endocarditis
- Skin and Skin Structure Infections
- Bone Infections
- Lower Respiratory Tract Infections

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYZAVAN™ and other antibacterial drugs, TYZAVAN™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

For more information about TYZAVAN™, please see the Full Prescribing Information or contact Hikma Pharmaceuticals USA Inc. at us.hikma@primevigilance.com or 1-877-845-0689.

You are encouraged to report negative side effects of prescription drugs to the FDA. 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.

Manufactured for:
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