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Press Release

Hikma receives FDA approval for TYZAVAN™ (Vancomycin Injection, USP) in the US

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

London, 02 July 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, today announced the approval of a novel formulation of the first-of-its-kind, ready-to-infuse formulation of vancomycin, under the brand name TYZAVAN™ (Vancomycin Injection, USP), by the US Food and Drug Administration (FDA).

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 purpose: delivering timely, simplified treatment when every minute counts. TYZAVAN™ is the only FDA-approved vancomycin product commercially available for all patients that is available at room temperature and requires no compounding, thawing, activation or dilution—reducing preparation steps and supporting faster treatment[1].

According to the 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 Dr Bill Larkins, President of Hikma Injectables. "TYZAVAN™, available in ready-to-infuse 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 dedicated and specialised commercial team will drive the launch of TYZAVAN™, ensuring its successful introduction and adoption in US hospitals."

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

- **Ready-to-infuse formulation** – removes the need for on-site preparation and IV compounding, reduces strain on pharmacy and nursing staff, minimizes handling risk and reduces risk of medication errors
- **Seven presentations (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

According to IQVIA, US sales of vancomycin injection were close to $200 million in 2024.

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[1] TYZAVAN™ is an improved formulation of VancoReady, with no box warning and no limitation of use during pregnancy
[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

- ENDS –

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, muscular and chest pain may occur with rapid TYZAVAN™ administration (e.g., over several minutes). The reactions may be more severe in pediatric patients.
- **Nephrotoxicity –** TYZAVAN™ can result in acute kidney injury (AKI), including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis.
- **Ototoxicity –** Ototoxicity has occurred in patients receiving vancomycin. It may be reversible or permanent. Ototoxicity manifests as tinnitus, hearing loss, dizziness or vertigo.
- **Severe Dermatologic Reactions –** 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.
- ***Clostridioides difficile*-Associated Diarrhea (CDAD) –** *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.
- **Hemorrhagic Occlusive Retinal Vasculitis (HORV) –** Hemorrhagic occlusive retinal vasculitis, 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.
- **Phlebitis and Other Administration Site Reactions –** Inflammation at the site of injection of vancomycin 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**.** Administration of vancomycin 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 the intrathecal (intralumbar or intraventricular) route or by the intraperitoneal route 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 clinically significant adverse reactions are described in the warnings and precautions section.

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.

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: TYZAVAN™ is indicated in pediatric patients (1 month and older) for the treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections and lower respiratory tract infections for whom appropriate dosing with this formulation can be achieved.

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.

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.

INDICATIONS AND USAGE

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

- Septicemia
- Infective Endocarditis
- Early-onset Prosthetic Valve Endocarditis
- Skin and Skin Structure Infections
- Bone Infections

- Lower Respiratory Tract Infections

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

TYZAVAN™ (Vancomycin Injection, USP) is supplied as a ready to use clear, colorless to light brown solution in single-dose flexible bags. The flexible bags are supplied in sealed aluminum overpouches. The bags are supplied in the following packages described in table 1 below:

Table 1: TYZAVAN™ PACKAGE INFORMATION

Strength of TYZAVAN™	NDC number	Packaging configuration
500 mg/100 mL (5 mg/mL)	0143-9471-06	Carton of six bags
500 mg/100 mL (5 mg/mL)	0143-9471-12	Carton of twelve bags
750 mg/150 mL (5 mg/mL)	0143-9468-06	Carton of six bags
750 mg/150 mL (5 mg/mL)	0143-9468-12	Carton of twelve bags
1 g/200 mL (5 mg/mL)	0143-9472-06	Carton of six bags
1 g/200 mL (5 mg/mL)	0143-9472-12	Carton of twelve bags
1.25 g/250 mL (5 mg/mL)	0143-9466-06	Carton of six bags
1.5 g/300 mL (5 mg/mL)	0143-9469-06	Carton of six bags
1.75 g/350 mL (5 mg/mL)	0143-9467-06	Carton of six bags
2 g/400 mL (5 mg/mL)	0143-9470-06	Carton of six bags

Storage

Store at 15°C to 25°C (59°F to 77ºF), in original package. Use within 28 days of removal from aluminum overpouch.

ENDING INFORMATION

Patient Counseling should be shared with the patient prior to administration.
For additional information, please refer to the Package Insert for full prescribing information.

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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