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Press Release

Hikma launches Vancomycin Hydrochloride for Injection, USP, in the US

London, 29 August 2023 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Vancomycin Hydrochloride (HCl) for Injection, USP, in 1.25g and 1.5g doses. The product has been launched in the US and is indicated for:

- the treatment of infections including septicemia, infective endocarditis, skin and skin structure infections, bone infections and lower respiratory tract infections due to susceptible isolates of methicillin-resistant Staphylococcus aureus (MRSA) and coagulase negative staphylococci
- patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins

According to IQVIA, US sales of Vancomycin HCl for Injection, 1.25g and 1.5g, were $42 million in the 12 months ending June 2023.

Hikma is a top three supplier of generic injectable medicines by volume in the US[1], with a growing portfolio of more than 150 products. We are continuously expanding our portfolio of essential medicines and introducing new dosage forms that enhance patient care.

- ENDS -

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

Hikma helps put better health within reach every day for millions of people 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 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 8,800 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

[1] Source: IQVIA MAT June 2023, generic injectable volumes by eaches, excluding branded generics and Becton Dickinson

bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

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.

Important Safety Information for Vancomycin HCl for Injection, USP, in 1.25g and 1.5g:

Please see package insert for referenced section numbering, where appropriate.

CONTRAINDICATIONS

Vancomycin hydrochloride for injection 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 vancomycin hydrochloride for injection administration. The reactions may be more severe in younger patients, particularly children, and in patients receiving concomitant muscle relaxant anesthetics.

  Rapid intravenous administration of vancomycin hydrochloride for injection may also be associated with "vancomycin infusion reaction", which manifests as pruritus and erythema that involves the face, neck and upper torso.

  Infusion-related adverse reactions are related to both the concentration and the rate of administration of vancomycin. Infusion-related adverse reactions may occur, however, at any rate or concentration.

  Administer vancomycin hydrochloride for injection in a diluted solution over a period of 60 minutes or greater to reduce the risk of infusion-related adverse reactions. In selected patients in need of fluid restriction, a concentration up to 10 mg/mL may be used; use of such higher concentrations may increase the risk of infusion-related adverse reactions. Administer prior to intravenous anesthetic agents when feasible. Stop the infusion if a reaction occurs.
- **Nephrotoxicity –** Vancomycin hydrochloride for injection can result in acute kidney injury (AKI), including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis. AKI is manifested by increasing blood urea nitrogen (BUN) and serum creatinine (Cr). The risk of AKI increases with higher vancomycin serum levels, prolonged exposure, concomitant administration of other nephrotoxic drugs, concomitant administration of piperacillin-tazobactam, volume depletion, pre-existing renal impairment and in critically ill patients and patients with co-morbid conditions that predispose to renal impairment.

  Monitor serum vancomycin concentrations and renal function in all patients receiving vancomycin hydrochloride for injection. More frequent monitoring is recommended in patients with comorbidities that predispose to impairment in renal function or are concomitantly receiving other nephrotoxic drugs, in critically ill patients, in patients with changing renal function, and in patients requiring higher therapeutic vancomycin levels. If acute kidney injury occurs, discontinue vancomycin hydrochloride for injection or reduce the dose.
- **Ototoxicity –** Ototoxicity has occurred in patients receiving vancomycin hydrochloride for injection. It may be transient or permanent. Ototoxicity manifests as tinnitus, hearing loss, dizziness or vertigo. The risk is higher in older patients, patients who are receiving higher doses, who have an underlying hearing loss, who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside or who have underlying renal impairment. Monitor for signs and symptoms of ototoxicity during therapy. Monitor serum vancomycin concentrations and renal function in all patients receiving parenteral vancomycin. Discontinue vancomycin hydrochloride for injection if ototoxicity occurs. Dosage of vancomycin hydrochloride for injection must be adjusted for patients with renal impairment. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.
- **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.

  Discontinue vancomycin hydrochloride for injection at the first appearance of signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD.

- **Clostridioides difficile-Associated Diarrhea –** Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including vancomycin hydrochloride for injection, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

  C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

  If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

  Clinically significant serum concentrations have been reported in some patients being treated for active C. difficile-induced pseudomembranous colitis after multiple oral doses of vancomycin.

  Prolonged use of vancomycin hydrochloride for injection may result in the overgrowth of nonsusceptible microorganisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. In rare instances, there have been reports of pseudomembranous colitis due to C. difficile developing in patients who received intravenous vancomycin hydrochloride for injection.
- **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 the intracameral or the intravitreal route 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 hydrochloride for injection. Patients who will undergo prolonged therapy with vancomycin hydrochloride for injection or those who are receiving concomitant drugs which may cause neutropenia should have periodic monitoring of the leukocyte count.
- **Phlebitis and Other Administration Site Reactions –** Inflammation at the site of injection of vancomycin hydrochloride for injection has been reported. Vancomycin hydrochloride for injection 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 hydrochloride for injection 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.

  Pain, tenderness, and necrosis occur with IM injection of vancomycin hydrochloride for injection or with inadvertent extravasation. Thrombophlebitis may occur, the frequency and severity of which can be minimized by administering the drug slowly as a dilute solution (2.5 to 5 g/L) and by rotation of venous access sites.

  Intraperitoneal administration during continuous ambulatory peritoneal dialysis (CAPD) can result in chemical peritonitis. Manifestations range from cloudy dialysate alone to a cloudy dialysate accompanied by variable degrees of abdominal pain and fever. This syndrome appears to be resolve after discontinuation of intraperitoneal vancomycin.
- **Development of Drug-Resistant Bacteria –** Prescribing vancomycin hydrochloride for injection 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 following clinically significant adverse reactions are described elsewhere in the labeling:

- Infusion Reactions [see Warnings and Precautions (5.1)]
- Nephrotoxicity [see Warnings and Precautions (5.2)]
- Ototoxicity [see Warnings and Precautions (5.3)]
- Clostridioides difficile-Associated Diarrhea [see Warnings and Precautions (5.5)]
- Hemorrhagic Occlusive Retinal Vasculitis [see Warnings and Precautions (5.6)]
- Neutropenia [see Warnings and Precautions (5.7)]

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following adverse reactions associated with the use of vancomycin hydrochloride for injection were identified in clinical trials:
Immune system disorders: Hypersensitivity reactions including anaphylaxis and "vancomycin infusion reaction" [see Warnings and Precautions (5.1)]
Skin and subcutaneous tissue disorders: Erythema (especially of the face, neck and upper torso) and pruritus which are manifestations of rashes including exfoliative dermatitis, toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), Linear IgA bullous dermatosis (LABD) [see Warnings and Precautions (5.4)].
Renal and urinary disorders: Acute kidney injury and interstitial nephritis
Ear and Labyrinth Disorders: Tinnitus, hearing loss, vertigo
Blood and Lymphatic System Disorders: Agranulocytosis, neutropenia, pancytopenia, leukopenia, thrombocytopenia, eosinophilia
Gastrointestinal Disorders: Pseudomembranous colitis [see Warnings and Precautions (5.5)]
Cardiac Disorders: Cardiac arrest, chest pain
General Disorders and Administration Site Conditions: General discomfort, fever, chills, phlebitis, injection site irritation, injection site pain and necrosis following intramuscular injection, chemical peritonitis following intraperitoneal administration (Vancomycin hydrochloride for injection is not approved for intramuscular and intraperitoneal administration) [see Warnings and Precautions (5.7)]
Laboratory Abnormalities: Elevated blood urea nitrogen, elevated serum creatinine
Musculoskeletal and connective tissue disorders: Muscle pain
Nervous system disorders: Dizziness
Respiratory, thoracic and mediastinal disorders: Wheezing, dyspnea
Vascular disorders: Hypotension, shock, vasculitis

Postmarketing Experience
The following adverse reactions have been identified during post approval use of vancomycin. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Skin and Subcutaneous Tissue Disorders: Drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) [see Warnings and Precautions (5.4)].

DRUG INTERACTIONS

Anesthetic Agents
Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing [see Warnings and Precautions (5.1) and Use in Specific Populations (8.4)].

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 function in patients receiving concomitant piperacillin/tazobactam and vancomycin. No pharmacokinetic interactions have been noted between piperacillin/tazobactam and vancomycin.

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
Risk Summary
There are no available data on vancomycin use in pregnant women to inform a drug associated risk of major birth defects or miscarriage. Available published data on vancomycin use in pregnancy during the second and third trimesters have not shown an association with adverse pregnancy related outcomes (see Data). Vancomycin did not show adverse developmental effects when administered intravenously to pregnant rats and rabbits during organogenesis at doses less than or equal to the recommended maximum human dose based on body surface

area (see Data).

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Lactation
Risk Summary
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. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for vancomycin and any potential adverse effects on the breastfed infant from vancomycin or from the underlying maternal condition.

Pediatric Use
Vancomycin hydrochloride for injection is indicated in pediatric patients (neonates and older). In pediatric patients, monitor vancomycin serum concentration and renal function when administering vancomycin hydrochloride for injection [see Dosage and Administration (2.2, 2.3) and Warnings and Precautions (5.2)]. More severe infusion related reactions related to vancomycin administration may occur in pediatric patients. Concomitant administration of vancomycin and intravenous anesthetic agents has been associated with erythema and histamine-like flushing in all patients including pediatric patients [see Warnings and Precautions (5.1)].

Geriatric Use
Vancomycin hydrochloride for injection 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 [see Dosage and Administration (2.2)], and it may be useful to monitor renal function [see Warnings and Precautions (5.2)].

DOSAGE AND ADMINISTRATION

Important Administration Instructions
To reduce the risk of infusion related adverse reactions, administer vancomycin hydrochloride for injection in a diluted solution over 60 minutes or greater [see Warnings and Precautions(5.1) and Adverse Reactions (6.1)]. Vancomycin hydrochloride for injection concentrations of no more than 5 mg/mL are recommended in adults [see Dosage and Administration (2.2)]. See also age-specific recommendations [see Dosage and Administration (2.3)]. In selected patients in need of fluid restriction, a concentration up to 10 mg/mL may be used [see Warnings and Precautions (5.1)].

Administer vancomycin hydrochloride for injection prior to intravenous anesthetic agents to reduce the risk of infusion related adverse reactions [see Warnings and Precautions (5.1)].

Administer vancomycin hydrochloride by a secure intravenous route of administration to avoid local irritation and phlebitis reactions [see Warnings and Precautions (5.8)].

The supplied lyophilized powder must be reconstituted and subsequently diluted prior to intravenous use [see Dosage and Administration (2.5)].

Dosage in Adult Patients With Normal Renal Function
The usual daily intravenous dose is 2 grams divided either as 500 mg every 6 hours or 1 g every 12 hours. Administer each dose over a period of 60 minutes or greater. Other patient factors, such as age or obesity, may call for modification of the usual intravenous daily dose.

Dosage in Pediatric Patients With Normal Renal Function
Pediatric Patients (Aged 1 month and older)
The usual intravenous dosage of vancomycin is 10 mg/kg per dose given every 6 hours. Each dose should be administered over a period of at least 60 minutes. Close monitoring of serum concentrations of vancomycin may be warranted in these patients.

Neonates (Up to 1 month old)
In pediatric patients, up to the age of 1 month, the total daily intravenous dosage may be lower. In neonates, an initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours for neonates in the 1st week of life and every 8 hours thereafter up to the age of 1 month. Each dose should be administered over 60 minutes. In

premature infants, vancomycin clearance decreases as postconceptional age decreases. Therefore, longer dosing intervals may be necessary in premature infants. Close monitoring of serum concentrations of vancomycin is recommended in these patients.

Dosage in Patients With Renal Impairment
Dosage adjustment must be made in patients with renal impairment. The initial dose should beno less than 15 mg/kg, in patients with any degree of renal impairment.

In premature infants and the elderly, greater dosage reductions than expected may be necessary because of decreased renal function. Measure trough vancomycin serum concentrations to guide therapy, especially in seriously ill patients with changing renal function.

For functionally anephric patients, an initial dose of 15 mg/kg of body weight should be given to achieve prompt therapeutic serum concentration. A dose of 1.9 mg/kg/24 hr should be given after the initial dose of 15 mg/kg.

Preparation of Vancomycin Hydrochloride for Injection for Intravenous Administration and Storage Instructions
Vancomycin hydrochloride for injection must be reconstituted and further diluted.

Reconstitution of the Lyophilized Powder and further dilution
At the time of use, reconstitute the vials of vancomycin hydrochloride for injection (lyophilized powder) with Sterile Water for Injection to a concentration of 50 mg of vancomycin/mL then further dilute with an infusion solution to a final concentration of 5 mg/mL (see Table 1 for the appropriate volumes). Discard any reconstituted solution remaining in the vial.

Table 1 Volume of Sterile Water for Injection to be Added for Reconstitution and Volume of Infusion Solution to be Used for Further Dilution

Vancomycin Strength per Vial	Volume of Sterile Water for Injection for reconstitution[a]	Volume of infusion solution[b] to further dilute to a final concentration of 5 mg/mL
1.25 g	25 mL	250 mL
1.5 g	30 mL	300 mL

[a]After reconstitution, the vials may be stored in a refrigerator for 14 days without significant loss of potency.
[b]Use an infusion solution from the list of the compatible infusion solutions below *[see Dosage and Administration (2.6)]*.

The desired dose diluted in this manner should be administered by intermittent IV infusion over a period of 60 minutes or greater.

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

Discard reconstituted and diluted solutions 14 days after initial reconstitution.

Compatibility with Intravenous Fluids
The following diluents are physically and chemically compatible with 5 g/L vancomycin hydrochloride:
5% Dextrose Injection, USP
5% Dextrose Injection and 0.9% Sodium Chloride Injection, USP
Lactated Ringer's Injection, USP
Lactated Ringer's and 5% Dextrose Injection, USP
0.9% Sodium Chloride Injection, USP

Storage of Diluted Solutions:
Solutions that are diluted with 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP may be stored in a refrigerator for 14 days without significant loss of potency.

Solutions that are diluted with the following infusion fluids may be stored in a refrigerator for 96 hours:
5% Dextrose Injection and 0.9% Sodium Chloride Injection, USP
Lactated Ringer's Injection, USP
Lactated Ringer's and 5% Dextrose Injection, USP

Incompatibilities for Intravenous Use
Vancomycin solution has a low pH and may cause chemical or physical instability when it is mixed with other compounds.
Mixtures of solutions of vancomycin and beta-lactam antibacterial drugs have been shown to be physically incompatible. The likelihood of precipitation increases with higher concentrations of vancomycin. It is recommended to adequately flush the intravenous lines between the administration of these antibacterial drugs. It is also recommended to dilute solutions of vancomycin to 5 mg/mL or less.

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.

INDICATIONS AND USAGE

Septicemia
Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of septicemia due to:

- Susceptible isolates of methicillin-resistant Staphylococcus aureus (MRSA) and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Infective Endocarditis
Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of infective endocarditis due to:

- Susceptible isolates of MRSA.
- Viridans group streptococci Streptococcus gallolyticus (previously known as Streptococcus bovis), Enterococcus species and Corynebacterium species. For enterococcal endocarditis, use vancomycin hydrochloride for injection in combination with an aminoglycoside.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of early-onset prosthetic valve endocarditis caused by Staphylococcus epidermidis in combination with rifampin and an aminoglycoside.

Skin and Skin Structure Infections
Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of skin and skin structure infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Bone Infections
Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of bone infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Lower Respiratory Tract Infections

Vancomycin hydrochloride for injection is indicated in adults and pediatric patients (neonates and older) for the treatment of lower respiratory tract infections due to:

- Susceptible isolates of MRSA
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Usage

To reduce the development of drug-resistant bacteria andmaintain the effectiveness of vancomycin hydrochloride for injection and other antibacterial drugs, vancomycin hydrochloride for injection 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.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied:

Vancomycin Hydrochloride for Injection, USP is a sterile lyophilized powder for injection supplied as an off-white to light tan colored powder or plug in single-dose flip top vials that contain vancomycin hydrochloride, USP equivalent to 1.25 g, or 1.5 g of vancomycin base. They are available as follows:

NDC 0143-9152-10: Vancomycin Hydrochloride for Injection, USP equivalent to 1.25 g vancomycin in a 50 mL flip top vial with a light violet seal, in packages of 10 vials.
NDC 0143-9153-10: Vancomycin Hydrochloride for Injection, USP equivalent to 1.5 g vancomycin in a 50 mL flip top vial with a white seal, in packages of 10 vials.

Storage:

Prior to reconstitution, store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]

ENDING INFORMATION

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.

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

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