

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VANCOCIN CAPSULES safely and effectively. See full prescribing information for VANCOCIN CAPSULES.

VANCOCIN® (vancomycin hydrochloride, USP) CAPSULES
Initial U.S. Approval: 1986

To reduce the development of drug-resistant bacteria and maintain the effectiveness of VANCOCIN CAPSULES and other antibacterial drugs, VANCOCIN CAPSULES should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

RECENT MAJOR CHANGES

Dosage and Administration (12/2011)

Warnings and Precautions (12/2011)

INDICATIONS AND USAGE

Treatment of: (1)

- *C. difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Important Limitations: (1) (5.1)

- Orally administered VANCOCIN is not effective for other types of infections.

DOSAGE AND ADMINISTRATION

- *C. difficile*-associated diarrhea:
 - Adult Patients (≥18 years of age): 125 mg orally 4 times daily for 10 days. (2.1)
 - Pediatric Patients (<18 years of age): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g. (2.2)
- Staphylococcal enterocolitis:
 - Adult Patients (≥18 years of age): 500 mg to 2 g orally in 3 or 4 divided doses for 7 to 10 days. (2.1)
 - Pediatric Patients (<18 years of age): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g. (2.2)

DOSAGE FORMS AND STRENGTHS

- 125 mg capsules (3)
- 250 mg capsules (3)

CONTRAINDICATIONS

Hypersensitivity to vancomycin (4)

WARNINGS/PRECAUTIONS

- VANCOCIN must be given orally for treatment of staphylococcal enterocolitis and *C. difficile*-associated diarrhea. Orally administered VANCOCIN CAPSULES are not effective for other types of infections. (5.1)
- Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of VANCOCIN for active *C. difficile*-associated diarrhea. Monitoring of serum concentrations may be appropriate in some instances. (5.2)
- Nephrotoxicity has occurred following oral VANCOCIN therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients (5.3) Monitor renal function.
- Ototoxicity has occurred in patients receiving VANCOCIN. (5.4) Assessment of auditory function may be appropriate in some instances.
- Prescribing VANCOCIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria. (5.6)

ADVERSE REACTIONS

The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%), and hypokalemia (13%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact ViroPharma at (888-651-0201) or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

DRUG INTERACTIONS

No drug interaction studies have been conducted. (7)

USE IN SPECIFIC POPULATIONS

- **Pediatrics:** Safety and effectiveness in patients <18 years of age have not been established. (8.4)
- **Geriatrics:** In patients >65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with VANCOCIN to detect potential vancomycin induced nephrotoxicity. (5.3) (6.1) (8.5) (14.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: December 2011

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2 **FULL PRESCRIBING INFORMATION**

3 **VANCOCIN® (vancomycin hydrochloride, USP) CAPSULES**

4 **1 INDICATIONS AND USAGE**

5 VANCOCIN CAPSULES are indicated for the treatment of *C. difficile*-associated
6 diarrhea. VANCOCIN CAPSULES are also used for the treatment of enterocolitis
7 caused by *Staphylococcus aureus* (including methicillin-resistant strains). Parenteral
8 administration of vancomycin is not effective for the above infections; therefore,
9 VANCOCIN CAPSULES must be given orally for these infections.

10 **Orally administered VANCOCIN is not effective for other types of infections.**

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

18 **2 DOSAGE AND ADMINISTRATION**

19 **2.1 Adults**

20 VANCOCIN CAPSULES are used in treating *C. difficile*-associated diarrhea and
21 staphylococcal enterocolitis.

- 22 • *C. difficile*-associated diarrhea: The recommended dose is 125 mg administered
23 orally 4 times daily for 10 days.
- 24 • Staphylococcal enterocolitis: Total daily dosage is 500 mg to 2 g administered
25 orally in 3 or 4 divided doses for 7 to 10 days.

26 **2.2 Pediatric Patients**

27 The usual daily dosage is 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total
28 daily dosage should not exceed 2 g.

29 **3 DOSAGE FORMS AND STRENGTHS**

30 VANCOCIN 125 mg* CAPSULES have an opaque blue cap and opaque brown body
31 imprinted with “3125” on the cap and “VANCOCIN HCL 125 MG” on the body in white
32 ink.

33 VANCOCIN 250 mg* CAPSULES have an opaque blue cap and opaque lavender body
34 imprinted with “3126” on the cap and “VANCOCIN HCL 250 MG” on the body in white
35 ink.

36 *Equivalent to vancomycin.

37 **4 CONTRAINDICATIONS**

38 VANCOCIN CAPSULES are contraindicated in patients with known hypersensitivity to
39 vancomycin.

40 **5 WARNINGS AND PRECAUTIONS**

41 **5.1 Oral Use Only**

42 **This preparation for the treatment of colitis is for oral use only and is not**
43 **systemically absorbed. VANCOCIN CAPSULES must be given orally for treatment**
44 **of staphylococcal enterocolitis and *Clostridium difficile*-associated diarrhea. Orally**
45 **administered VANCOCIN CAPSULES are not effective for other types of**
46 **infections.**

47 **Parenteral administration of vancomycin is *not* effective for treatment of**
48 **staphylococcal enterocolitis and *C. difficile*-associated diarrhea. If parenteral**
49 **vancomycin therapy is desired, use an intravenous preparation of vancomycin and**
50 **consult the package insert accompanying that preparation.**

51 **5.2 Potential for Systemic Absorption**

52 Clinically significant serum concentrations have been reported in some patients who have
53 taken multiple oral doses of VANCOCIN for active *C. difficile*-associated diarrhea. Some
54 patients with inflammatory disorders of the intestinal mucosa also may have significant
55 systemic absorption of vancomycin. These patients may be at risk for the development of
56 adverse reactions associated with higher doses of VANCOCIN; therefore, monitoring of
57 serum concentrations of vancomycin may be appropriate in some instances, e.g., in
58 patients with renal insufficiency and/or colitis or in those receiving concomitant therapy
59 with an aminoglycoside antibiotic.

60 **5.3 Nephrotoxicity**

61 Nephrotoxicity (e.g., reports of renal failure, renal impairment, blood creatinine
62 increased) has occurred following oral VANCOCIN therapy in randomized controlled
63 clinical studies, and can occur either during or after completion of therapy.

64 The risk of nephrotoxicity is increased in patients >65 years of age (*see ADVERSE*
65 *REACTIONS, Clinical Trial Experience [6.1] and USE IN SPECIFIC POPULATIONS,*
66 *Geriatric Use [8.5]*).

67 In patients >65 years of age, including those with normal renal function prior to
68 treatment, renal function should be monitored during and following treatment with
69 VANCOGIN to detect potential vancomycin induced nephrotoxicity.

70 **5.4 Ototoxicity**

71 Ototoxicity has occurred in patients receiving vancomycin. It may be transient or
72 permanent. It has been reported mostly in patients who have been given excessive
73 intravenous doses, who have an underlying hearing loss, or who are receiving
74 concomitant therapy with another ototoxic agent, such as an aminoglycoside. Serial tests
75 of auditory function may be helpful in order to minimize the risk of ototoxicity (*see*
76 *ADVERSE REACTIONS, Postmarketing Experience [6.2]*).

77 **5.5 Superinfection**

78 Use of VANCOGIN may result in the overgrowth of nonsusceptible bacteria. If
79 superinfection occurs during therapy, appropriate measures should be taken.

80 **5.6 Development of Drug-Resistant Bacteria**

81 Prescribing VANCOGIN in the absence of a proven or strongly suspected bacterial
82 infection is unlikely to provide benefit to the patient and increases the risk of the
83 development of drug resistant bacteria.

84 **6 ADVERSE REACTIONS**

85 **6.1 Clinical Trial Experience**

86 Because clinical studies are conducted under widely varying conditions, adverse reaction
87 rates observed in the clinical studies of a drug cannot be directly compared to rates in the
88 clinical studies of another drug and may not reflect the rates observed in practice.

89 The data described below reflect exposure to VANCOGIN in 260 adult subjects in two
90 Phase 3 clinical trials for the treatment of diarrhea associated with *C. difficile*. In both
91 trials, subjects received VANCOGIN 125 mg orally four times daily. The mean duration
92 of treatment was 9.4 days. The median age of patients was 67, ranging between 19 and 96
93 years of age. Patients were predominantly Caucasian (93%) and 52% were male.

94 Adverse reactions occurring in $\geq 5\%$ of VANCOCIN-treated subjects are shown in Table
 95 1. The most common adverse reactions associated with VANCOCIN ($\geq 10\%$) were
 96 nausea, abdominal pain, and hypokalemia.

97 **Table 1: Common ($\geq 5\%$) Adverse Reactions^a for VANCOCIN Reported in Clinical Trials for**
 98 **Treatment of Diarrhea Associated with *C. difficile***

System/Organ Class	Adverse Reaction	VANCOCIN % (N=260)
Gastrointestinal disorders	Nausea	17
	Abdominal pain	15
	Vomiting	9
	Diarrhea	9
	Flatulence	8
General disorders and administration site conditions	Pyrexia	9
	Edema peripheral	6
	Fatigue	5
Infections and infestations	Urinary tract infection	8
Metabolism and nutrition disorders	Hypokalemia	13
Musculoskeletal and connective tissue disorders	Back pain	6
Nervous system disorders	Headache	7
^a Adverse reaction rates were derived from the incidence of treatment-emergent adverse events.		

99 Nephrotoxicity (e.g., reports of renal failure, renal impairment, blood creatinine
 100 increased) occurred in 5% of subjects treated with VANCOCIN. Nephrotoxicity
 101 following VANCOCIN typically first occurred within one week after completion of
 102 treatment (median day of onset was Day 16). Nephrotoxicity following VANCOCIN
 103 occurred in 6% of subjects >65 years of age and 3% of subjects ≤ 65 years of age (*see*
 104 *WARNINGS AND PRECAUTIONS, Nephrotoxicity [5.3]*).

105 The incidences of hypokalemia, urinary tract infection, peripheral edema, insomnia,
 106 constipation, anemia, depression, vomiting, and hypotension were higher among subjects
 107 >65 years of age than in subjects ≤ 65 years of age (*see USE IN SPECIFIC*
 108 *POPULATIONS, Geriatric Use [8.5]*).

109 Discontinuation of study drug due to adverse events occurred in 7% of subjects treated
 110 with VANCOCIN. The most common adverse events leading to discontinuation of
 111 VANCOCIN were *C. difficile* colitis ($<1\%$), nausea ($<1\%$), and vomiting ($<1\%$).

112 **6.2 Postmarketing Experience**

113 The following adverse reactions have been identified during post-approval use of
114 VANCOGIN. Because these reactions are reported voluntarily from a population of
115 uncertain size, it is not always possible to reliably estimate their frequency or establish a
116 causal relationship to drug exposure.

117 *Ototoxicity.* Cases of hearing loss associated with intravenously administered
118 vancomycin have been reported. Most of these patients had kidney dysfunction or a
119 preexisting hearing loss or were receiving concomitant treatment with an ototoxic drug
120 (*see WARNINGS AND PRECAUTIONS, Ototoxicity [5.4]*). Vertigo, dizziness, and
121 tinnitus have been reported.

122 *Hematopoietic.* Reversible neutropenia, usually starting 1 week or more after onset of
123 intravenous therapy with vancomycin or after a total dose of more than 25 g, has been
124 reported for several dozen patients. Neutropenia appears to be promptly reversible when
125 vancomycin is discontinued. Thrombocytopenia has been reported.

126 *Miscellaneous.* Patients have been reported to have had anaphylaxis, drug fever, chills,
127 nausea, eosinophilia, rashes (including exfoliative dermatitis), Stevens-Johnson
128 syndrome, toxic epidermal necrolysis, and rare cases of vasculitis in association with the
129 administration of vancomycin.

130 A condition has been reported that is similar to the IV-induced syndrome with symptoms
131 consistent with anaphylactoid reactions, including hypotension, wheezing, dyspnea,
132 urticaria, pruritus, flushing of the upper body (“Red Man Syndrome”), pain and muscle
133 spasm of the chest and back. These reactions usually resolve within 20 minutes but may
134 persist for several hours.

135 **7 DRUG INTERACTIONS**

136 No drug interaction studies have been conducted.

137 **8 USE IN SPECIFIC POPULATIONS**

138 **8.1 Pregnancy**

139 Pregnancy Category B – The highest doses of vancomycin tested were not teratogenic in
140 rats given up to 200 mg/kg/day IV (1180 mg/m² or 1 times the recommended maximum
141 human dose based on body surface area) or in rabbits given up to 120 mg/kg/day IV
142 (1320 mg/m² or 1.1 times the recommended maximum human dose based body surface
143 area). No effects on fetal weight or development were seen in rats at the highest dose

144 tested or in rabbits given 80 mg/kg/day (880 mg/m² or 0.74 times the recommended
145 maximum human dose based on body surface area).

146 In a controlled clinical study, the potential ototoxic and nephrotoxic effects of
147 vancomycin on infants were evaluated when the drug was administered intravenously to
148 pregnant women for serious staphylococcal infections complicating intravenous drug
149 abuse. Vancomycin was found in cord blood. No sensorineural hearing loss or
150 nephrotoxicity attributable to vancomycin was noted. One infant whose mother received
151 vancomycin in the third trimester experienced conductive hearing loss that was not
152 attributed to the administration of vancomycin. Because the number of subjects treated in
153 this study was limited and vancomycin was administered only in the second and third
154 trimesters, it is not known whether vancomycin causes fetal harm. Because animal
155 reproduction studies are not always predictive of human response, VANCOCIN should
156 be given to a pregnant woman only if clearly needed.

157 **8.3 Nursing Mothers**

158 Vancomycin is excreted in human milk based on information obtained with the
159 intravenous administration of vancomycin. However, systemic absorption of
160 vancomycin is very low following oral administration of VANCOCIN (*see CLINICAL*
161 *PHARMACOLOGY, Pharmacokinetics [12.3]*). It is not known whether vancomycin is
162 excreted in human milk, as no studies of vancomycin concentration in human milk after
163 oral administration have been done. Caution should be exercised when VANCOCIN is
164 administered to a nursing woman. Because of the potential for adverse events, a decision
165 should be made whether to discontinue nursing or discontinue the drug, taking into
166 account the importance of the drug to the mother.

167 **8.4 Pediatric Use**

168 Safety and effectiveness in pediatric patients have not been established.

169 **8.5 Geriatric Use**

170 In clinical trials, 54% of VANCOCIN-treated subjects were >65 years of age. Of these,
171 40% were between the ages of >65 and 75, and 60% were >75 years of age.

172 Clinical studies with VANCOCIN in diarrhea associated with *Clostridium difficile* have
173 demonstrated that geriatric subjects are at increased risk of developing nephrotoxicity
174 following treatment with oral VANCOCIN, which may occur during or after completion
175 of therapy. In patients >65 years of age, including those with normal renal function prior
176 to treatment, renal function should be monitored during and following treatment with
177 VANCOCIN to detect potential vancomycin induced nephrotoxicity (*see WARNINGS*

178 *AND PRECAUTIONS, Nephrotoxicity [5.3]; ADVERSE REACTIONS, Clinical Trial*
179 *Experience [6.1] and CLINICAL STUDIES, Diarrhea Associated with Clostridium*
180 *difficile [14.1]).*

181

182 Patients >65 years of age may take longer to respond to therapy compared to patients ≤65
183 years of age (see *CLINICAL STUDIES, Diarrhea Associated with Clostridium difficile*
184 *[14.1]*). Clinicians should be aware of the importance of appropriate duration of
185 VANCOCIN treatment in patients >65 years of age and not discontinue or switch to
186 alternative treatment prematurely.

187

188 **10 OVERDOSAGE**

189 Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is
190 poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin
191 have been reported to result in increased vancomycin clearance.

192 To obtain up-to-date information about the treatment of overdose, a good resource is your
193 certified Regional Poison Control Center. Telephone numbers of certified poison control
194 centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage,
195 consider the possibility of multiple drug overdoses, interaction among drugs, and unusual
196 drug kinetics.

197 **11 DESCRIPTION**

198 VANCOCIN CAPSULES for oral administration contain chromatographically purified
199 vancomycin hydrochloride, a tricyclic glycopeptide antibiotic derived from
200 *Amycolatopsis orientalis* (formerly *Nocardia orientalis*), which has the chemical formula
201 $C_{66}H_{75}Cl_2N_9O_{24} \cdot HCl$. The molecular weight of vancomycin hydrochloride is 1485.73;
202 500 mg of the base is equivalent to 0.34 mmol.

203 The capsules contain vancomycin hydrochloride equivalent to 125 mg (0.08 mmol) or
204 250 mg (0.17 mmol) vancomycin. The capsules also contain F D & C Blue No. 2,
205 gelatin, iron oxide, polyethylene glycol, titanium dioxide, and other inactive ingredients.

227 **12.4 Microbiology**

228 Mechanism of action

229 The bactericidal action of vancomycin against *Staphylococcus aureus* and the vegetative
230 cells of *Clostridium difficile* results primarily from inhibition of cell-wall biosynthesis.
231 In addition, vancomycin alters bacterial-cell-membrane permeability and RNA synthesis.

232 Mechanism of resistance

233 *Staphylococcus aureus*

234 *S. aureus* isolates with vancomycin minimal inhibitory concentrations (MICs) as
235 high as 1024 mcg/mL have been reported.

236 The exact mechanism of this resistance is not clear but is believed to be due to
237 cell wall thickening and potentially the transfer of genetic material.

238 *Clostridium difficile*

239 Isolates of *C. difficile* generally have vancomycin MICs of <1 mcg/mL, however
240 vancomycin MICs ranging from 4 mcg/mL to 16 mcg/mL have been reported.

241 The mechanism which mediates *C. difficile's* decreased susceptibility to
242 vancomycin has not been fully elucidated.

243 Vancomycin has been shown to be active against susceptible isolates of the following
244 bacteria in clinical infections as described in the INDICATIONS AND USAGE section.

245 Gram-positive bacteria

246 *Staphylococcus aureus* (including methicillin-resistant isolates) associated with
247 enterocolitis

248 Anaerobic Gram-positive bacteria

249 *Clostridium difficile* isolates associated with *C. difficile* associated diarrhea.

250 **13 NONCLINICAL TOXICOLOGY**

251 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

252 No long-term carcinogenesis studies in animals have been conducted.

253 At concentrations up to 1000 µg/mL, vancomycin had no mutagenic effect *in vitro* in the
254 mouse lymphoma forward mutation assay or the primary rat hepatocyte unscheduled
255 DNA synthesis assay. The concentrations tested *in vitro* were above the peak plasma
256 vancomycin concentrations of 20 to 40 µg/mL usually achieved in humans after slow
257 infusion of the maximum recommended dose of 1 g. Vancomycin had no mutagenic

258 effect *in vivo* in the Chinese hamster sister chromatid exchange assay (400 mg/kg IP) or
259 the mouse micronucleus assay (800 mg/kg IP).

260 No definitive fertility studies have been conducted.

261 **14 CLINICAL STUDIES**

262 **14.1 Diarrhea Associated with *Clostridium difficile***

263 In two trials, VANCOCIN 125 mg orally four times daily for 10 days was evaluated in
264 266 adult subjects with *C. difficile*-associated diarrhea (CDAD). Enrolled subjects were
265 18 years of age or older and received no more than 48 hours of treatment with oral
266 VANCOCIN or oral/intravenous metronidazole in the 5 days preceding enrollment.
267 CDAD was defined as ≥ 3 loose or watery bowel movements within the 24 hours
268 preceding enrollment, and the presence of either *C. difficile* toxin A or B, or
269 pseudomembranes on endoscopy within the 72 hours preceding enrollment. Subjects with
270 fulminant *C. difficile* disease, sepsis with hypotension, ileus, peritoneal signs or severe
271 hepatic disease were excluded.

272

273 Efficacy analyses were performed on the Full Analysis Set (FAS), which included
274 randomized subjects who received at least one dose of VANCOCIN and had any post-
275 dosing investigator evaluation data (N=259; 134 in Trial 1 and 125 in Trial 2).

276

277 The demographic profile and baseline CDAD characteristics of enrolled subjects were
278 similar in the two trials. VANCOCIN-treated subjects had a median age of 67 years, were
279 mainly white (93%), and male (52%). CDAD was classified as severe (defined as 10 or
280 more unformed bowel movements per day or $WBC \geq 15000/mm^3$) in 25% of subjects, and
281 47% were previously treated for CDAD.

282

283 Efficacy was assessed by using clinical success, defined as diarrhea resolution and the
284 absence of severe abdominal discomfort due to CDAD, on Day 10. An additional
285 efficacy endpoint was the time to resolution of diarrhea, defined as the beginning of
286 diarrhea resolution that was sustained through the end of the prescribed active treatment
287 period.

288

289 The results for clinical success for VANCOCIN-treated subjects in both trials are shown
290 in Table 2.

291

292 **Table 2: Clinical Success Rates (Full Analysis Set)**

	Clinical Success Rate	95% Confidence Interval
	VANCOGIN % (N)	
Trial 1	81.3 (134)	(74.4, 88.3)
Trial 2	80.8 (125)	(73.5, 88.1)

293
 294 The median time to resolution of diarrhea was 5 days and 4 days in Trial 1 and Trial 2,
 295 respectively. For subjects older than 65 years of age, the median time to resolution was 6
 296 days and 4 days in Trial 1 and Trial 2, respectively. In subjects with diarrhea resolution
 297 at end-of-treatment with VANCOGIN, recurrence of CDAD during the following four
 298 weeks occurred in 25 of 107 (23%) and 18 of 102 (18%) in Trial 1 and Trial 2,
 299 respectively.

300
 301 Restriction Endonuclease Analysis (REA) was used to identify *C. difficile* baseline
 302 isolates in the BI group. In Trial 1, the Vancocin-treated subjects were classified at
 303 baseline as follows 31 (23%) with BI strain, 69 (52%) with non-BI strain, and 34 (25%)
 304 with unknown strain. Clinical success rates were 87% for BI strain, 81% for non-BI
 305 strain, and 76% for unknown strain. In subjects with diarrhea resolution at end-of
 306 treatment with VANCOGIN, recurrence of CDAD during the following four weeks
 307 occurred in 7 of 26 subjects with BI strain, 12 of 56 subjects with non-BI strain, and 6 of
 308 25 subjects with unknown strain.

309
 310 **16 HOW SUPPLIED/STORAGE AND HANDLING**

311 VANCOGIN CAPSULES are available in:

312
 313 The 125 mg* capsules have an opaque blue cap and opaque brown body imprinted with
 314 “3125” on the cap and “VANCOGIN HCL 125 MG” on the body in white ink. A carton
 315 contains 2 blister packs. Each blister pack contains 10 capsules for a total of 20 capsules
 316 per carton. NDC 66593-3125-2 (PU3125)

317
 318 The 250 mg* capsules have an opaque blue cap and opaque lavender body imprinted with
 319 “3126” on the cap and “VANCOGIN HCL 250 MG” on the body in white ink. A carton
 320 contains 2 blister packs. Each blister pack contains 10 capsules for a total of 20 capsules
 321 per carton. NDC 66593-3126-2 (PU3126)

322
 323 Store at controlled room temperature, 59° to 86°F (15° to 30°C).

324
 325 *Equivalent to vancomycin.

326

327 **17 PATIENT COUNSELING INFORMATION**

328 Patients should be counseled that antibacterial drugs including VANCOCIN should only
329 be used to treat bacterial infections. They do not treat viral infections (e.g., the common
330 cold). When VANCOCIN is prescribed to treat a bacterial infection, patients should be
331 told that although it is common to feel better early in the course of therapy, the
332 medication should be taken exactly as directed. Skipping doses or not completing the full
333 course of therapy may (1) decrease the effectiveness of the immediate treatment and (2)
334 increase the likelihood that bacteria will develop resistance and will not be treatable by
335 VANCOCIN or other antibacterial drugs in the future.

336

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