

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204300Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

VAZCULEP (phenylephrine hydrochloride) Injection for intravenous use
Initial U.S. Approval: 1954

INDICATIONS AND USAGE

VAZCULEP (phenylephrine hydrochloride) Injection is an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. (1)

DOSAGE AND ADMINISTRATION

VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL, is injected intravenously either as a bolus or in a dilute solution as a continuous infusion. Dilute before administration. (2)

Dosing for treatment of hypotension during anesthesia

- Bolus intravenous injection: 40 mcg to 100 mcg every 1-2 minutes as needed, not to exceed 200 mcg. (2)
- Intravenous infusion: 10 mcg/min to 35 mcg/min, titrating to effect, not to exceed 200 mcg/min. (2)

The dose should be adjusted according to the pressor response (i.e., titrate to effect). (2)

DOSAGE FORMS AND STRENGTHS

- Injection (3)
- 1 mL single use vials containing 10 mg phenylephrine hydrochloride (10 mg/mL) (3)
- 5 mL pharmacy bulk package vials containing 50 mg phenylephrine hydrochloride (10 mg/mL) (3)
- 10 mL pharmacy bulk package vials containing 100 mg phenylephrine hydrochloride (10 mg/mL) (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- *Extravasation during intravenous administration may cause necrosis or sloughing of tissue* (5.3)
- *Severe bradycardia and decreased cardiac output* (5.4)
- *Allergic-type reactions: Sulfite* (5.5)
- *Concomitant use with oxytocic drugs* Pressor effect of sympathomimetic pressor amines is potentiated (5.8)

ADVERSE REACTIONS

Most common adverse reactions during treatment: nausea, vomiting, and headache. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Éclat Pharmaceuticals at 1-877-622-2320 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Agonistic effects with monoamine oxidase inhibitors (MAOI), oxytocin and oxytocic drugs, , tricyclic antidepressants, angiotensin and aldosterone, atropine, steroids, norepinephrine transporter inhibitors, ergot alkaloids (7.1)
- Antagonistic effects with α -adrenergic antagonists, phosphodiesterase Type 5 inhibitors, mixed α - and β -receptor antagonists, calcium channel blockers, benzodiazepines and ACE inhibitors, centrally acting sympatholytic agents (7.2)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm. (8.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 6/2014

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1 FULL PRESCRIBING INFORMATION

2 1 INDICATIONS AND USAGE

3 VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL is an alpha-1 adrenergic
4 receptor agonist indicated for the treatment of clinically important hypotension resulting
5 primarily from vasodilation in the setting of anesthesia.

6 2 DOSAGE AND ADMINISTRATION

7 2.1 General Dosage and Administration Instructions

8 VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL must be diluted before
9 administration as an intravenous bolus or continuous intravenous infusion to achieve the desired
10 concentration:

- 11 • Bolus: Dilute with normal saline or 5% dextrose in water.
- 12 • Continuous infusion: Dilute with normal saline or 5% dextrose in water.

13 Parenteral drug products should be inspected visually for particulate matter and discoloration
14 prior to administration. Do not use if the solution is colored or cloudy, or if it contains particulate
15 matter. The diluted solution should not be held for more than 4 hours at room temperature or for
16 more than 24 hours under refrigerated conditions. Discard any unused portion.

17 During VAZCULEP administration:

- 18 • Correct intravascular volume depletion.
- 19 • Correct acidosis. Acidosis may reduce the effectiveness of phenylephrine.

20 2.2 Dosing for Treatment of Hypotension during Anesthesia

21 The following are the recommended dosages for the treatment of hypotension during anesthesia.

- 22 • The recommended initial dose is 40 to 100 mcg administered by intravenous bolus.
23 May administer additional boluses every 1-2 minutes as needed; not to exceed a total
24 dosage of 200 mcg.
- 25 • If blood pressure is below the target goal, start a continuous intravenous infusion with
26 an infusion rate of 10 to 35 mcg/minute; not to exceed 200 mcg/minute.
- 27 • Adjust dosage according to the blood pressure goal.

28 2.3 Prepare a 100 mcg/mL Solution for Bolus Intravenous 29 Administration

30 For bolus intravenous administration, prepare a solution containing a final concentration of 100
31 mcg/mL of VAZCULEP:

- 32 • Withdraw 10 mg (1 mL of 10 mg/mL) of VAZCULEP and dilute with 99 mL of 5%
33 Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP.
- 34 • Withdraw an appropriate dose from the 100 mcg/mL solution prior to bolus
35 intravenous administration.

36 **2.4 Prepare a Solution for Continuous Intravenous Administration**

37 For continuous intravenous infusion, prepare a solution containing a final concentration of 20
38 mcg/mL of VAZCULEP in 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection,
39 USP:

- 40 • Withdraw 10 mg (1 mL of 10 mg/mL) of VAZCULEP and dilute with 500 mL of 5%
41 Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP.

42 **2.5 Directions for Dispensing from Pharmacy Bulk Vial**

43 The Pharmacy Bulk Vial is intended for dispensing of single doses to multiple patients in a
44 pharmacy admixture program and is restricted to the preparation of admixtures for infusion. Each
45 closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set
46 that allows measured dispensing of the contents. The Pharmacy Bulk Vial is to be used only in a
47 suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
48 Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is
49 penetrated.

50 **3 DOSAGE FORMS AND STRENGTHS**

51 VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL is available in three vial sizes:

- 52 • Injection: 10 mg/mL in a single dose 1 mL vial (10 mg of phenylephrine
53 hydrochloride per vial)
- 54 • Injection: 10 mg/mL in Pharmacy Bulk Package 5 mL vial (50 mg of phenylephrine
55 hydrochloride per vial) that will provide five 1 mL single doses
- 56 • Injection: 10 mg/mL in Pharmacy Bulk Package 10 mL vial (100 mg of
57 phenylephrine hydrochloride per vial) that will provide ten 1 mL single doses

58 **4 CONTRAINDICATIONS**

59 None

60 **5 WARNINGS AND PRECAUTIONS**

61 **5.1 Exacerbation of Angina, Heart Failure, or Pulmonary Arterial**
62 **Hypertension**

63 Because of its increasing blood pressure effects, VAZCULEP can precipitate angina in patients
64 with severe arteriosclerosis or history of angina, exacerbate underlying heart failure, and increase
65 pulmonary arterial pressure.

66 **5.2 Peripheral and Visceral Ischemia**

67 VAZCULEP can cause excessive peripheral and visceral vasoconstriction and ischemia to vital
68 organs, particularly in patients with extensive peripheral vascular disease.

69 **5.3 Skin and Subcutaneous Necrosis**

70 Extravasation of VAZCULEP can cause necrosis or sloughing of tissue. The infusion site should
71 be checked for free flow. Care should be taken to avoid extravasation of VAZCULEP.

72 **5.4 Bradycardia**

73 VAZCULEP can cause severe bradycardia and decreased cardiac output.

74 **5.5 Allergic Reactions**

75 VAZCULEP contains sodium metabisulfite, a sulfite that may cause allergic-type reactions,
76 including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain
77 susceptible people. The overall prevalence of sulfite sensitivity in the general population is
78 unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in
79 nonasthmatic people.

80 **5.6 Renal Toxicity**

81 VAZCULEP can increase the need for renal replacement therapy in patients with septic shock.
82 Monitor renal function.

83 **5.7 Risk of Augmented Pressor Affect in Patients with Autonomic**
84 **Dysfunction**

85 The increasing blood pressure response to adrenergic drugs, including VAZCULEP, can be
86 increased in patients with autonomic dysfunction, as may occur with spinal cord injuries.

87 **5.8 Pressor Effect with Concomitant Oxytocic Drugs**

88 Oxytocic drugs potentiate the increasing blood pressure effect of sympathomimetic pressor
89 amines including VAZCULEP [*see Drug Interactions (7.1)*], with the potential for hemorrhagic
90 stroke.

91 **6 ADVERSE REACTIONS**

92 Adverse reactions to VAZCULEP are primarily attributable to excessive pharmacologic activity.
93 Adverse reactions reported in published clinical studies, observational trials, and case reports of
94 VAZCULEP are listed below by body system. Because these reactions are reported voluntarily
95 from a population of uncertain size, it is not always possible to estimate their frequency reliably
96 or to establish a causal relationship to drug exposure.

97 *Cardiac disorders:* Reflex bradycardia, lowered cardiac output, ischemia, hypertension,
98 arrhythmias

99 *Gastrointestinal disorders:* Epigastric pain, vomiting, nausea

100 *Nervous system disorders:* Headache, blurred vision, neck pain, tremors

101 *Vascular disorders:* Hypertensive crisis

102 *Respiratory, Thoracic and Mediastinal Disorders:* Dyspnea

103 *Skin and subcutaneous tissue disorders:* Pruritis

104 **7 DRUG INTERACTIONS**

105 **7.1 Interactions that Augment Pressor Effect**

106 The increasing blood pressure effect of VAZCULEP is *increased* in patients receiving:

- 107 • Monoamine oxidase inhibitors (MAOI)
- 108 • Oxytocin and oxytocic drugs
- 109 • Tricyclic antidepressants
- 110 • Angiotensin, aldosterone
- 111 • Atropine
- 112 • Steroids, such as hydrocortisone
- 113 • Norepinephrine transporter inhibitors, such as atomoxetine
- 114 • Ergot alkaloids, such as methylergonovine maleate

115 **7.2 Interactions that Antagonize the Pressor Effect**

116 The increasing blood pressure effect of VAZCULEP is *decreased* in patients receiving:

- 117 • α -adrenergic antagonists
- 118 • Phosphodiesterase Type 5 inhibitors
- 119 • Mixed α - and β -receptor antagonists
- 120 • Calcium channel blockers, such as nifedipine
- 121 • Benzodiazepines

- 122 • ACE inhibitors
- 123 • Centrally acting sympatholytic agents, such as reserpine, guanfacine.

124 **8 USE IN SPECIFIC POPULATIONS**

125 **8.1 Pregnancy**

126 Pregnancy Category C

127 *Risk Summary*

128 There are no adequate or well-controlled studies with phenylephrine hydrochloride injection in
129 pregnant women, nor have animal reproduction studies been conducted. Published studies in
130 normotensive pregnant rabbits report early onset labor, increased fetal lethality, and adverse
131 placental effects with subcutaneous phenylephrine administration during gestation at doses
132 approximately 1.9-times the total daily human dose. Published studies in normotensive pregnant
133 sheep report decreased uterine blood flow and decreased PaO₂ in the fetus with intravenous
134 phenylephrine administration during late gestation at doses less than and similar to the human
135 dose. It is not known whether VAZCULEP, can cause fetal harm when administered to a
136 pregnant woman. VAZCULEP, should be given to a pregnant woman only if the potential
137 benefit justifies the potential risk to the fetus.

138 *Clinical Considerations*

139 Labor and Delivery

140 The most common maternal adverse reactions reported in published studies of phenylephrine use
141 during neuraxial anesthesia during Cesarean delivery include nausea and vomiting, bradycardia,
142 reactive hypertension, and transient arrhythmias. Phenylephrine, when administered during labor
143 or delivery, does not appear to alter either neonatal Apgar scores or umbilical artery blood-gas
144 status.

145 *Data*

146 Animal Data

147 Studies in the published literature evaluating subcutaneously administered phenylephrine (0.33
148 mg/kg, TID) in normotensive pregnant rabbits reported fetal deaths, adverse histopathology
149 findings in the placenta (necrosis, calcification and thickened vascular walls with narrowed
150 lumen) and possible teratogenic effects (one incidence of clubbed feet, partial development of
151 the intestine) when treatment was initiated during the first trimester or later; and premature labor
152 when treatment was initiated at the second trimester or later. The doses administered were 1.9-
153 times the total daily human dose of 10 mg/day based on a body surface area comparison.
154 Published studies in pregnant normotensive sheep demonstrate that intravenous phenylephrine (4
155 mcg/kg/min for 30 minutes, equivalent to 3.6 to 4.1 mcg/kg/min human equivalent dose based on
156 body surface area) administered during the third trimester of pregnancy decreased uterine blood
157 flow by 42%. This dose is 1.1- to 1.2-times the human bolus dose of 200 mcg/60 kg person
158 based on body surface area. Mean fetal blood pressure and heart rate fluctuated above and below
159 controls by about 7% during the infusion. Fetal PaO₂ was significantly decreased by
160 approximately 26% of control during the infusion. Likewise, PaCO₂ was increased and pH was

161 decreased. The clinical significance of these findings is not clear; however, the results suggest
162 the potential for cardiovascular effects on the fetus when phenylephrine is used during
163 pregnancy.

164 **8.3 Nursing Mothers**

165 It is not known whether phenylephrine is present in human milk. The developmental and health
166 benefits of breastfeeding should be considered along with the mother's clinical need for
167 VAZCULEP and any potential adverse effects on the breastfed child from the drug or from the
168 underlying maternal condition. Exercise caution when VAZCULEP is administered to a nursing
169 woman.

170 **8.4 Pediatric Use**

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

172 **8.5 Geriatric Use**

173 Clinical studies of phenylephrine did not include sufficient numbers of subjects aged 65 and over
174 to determine whether they respond differently from younger subjects. Other reported clinical
175 experience has not identified differences in responses between the elderly and younger patients.
176 In general, dose selection for an elderly patient should be cautious, usually starting at the low end
177 of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac
178 function, and of concomitant disease or other drug therapy.

179 **8.6 Hepatic Impairment**

180 In patients with liver cirrhosis [Child Pugh Class B and Class C], dose-response data indicate
181 decreased responsiveness to phenylephrine. Start dosing in the recommended dose range but
182 consider that you may need to give more phenylephrine in this population.

183 **8.7 Renal Impairment**

184 In patients with end stage renal disease (ESRD), dose-response data indicate increased
185 responsiveness to phenylephrine. Consider starting at the lower end of the recommended dose
186 range, and adjusting dose based on the target blood pressure goal.

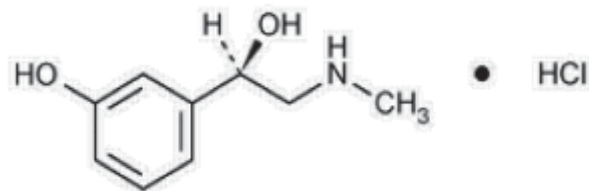
187 **10 OVERDOSAGE**

188 Overdose of VAZCULEP can cause a rapid rise in blood pressure. Symptoms of overdose
189 include headache, vomiting, hypertension, reflex bradycardia, a sensation of fullness in the head,
190 tingling of the extremities, and cardiac arrhythmias including ventricular extrasystoles and
191 ventricular tachycardia.

192 **11 DESCRIPTION**

193 Phenylephrine is an alpha-1 adrenergic receptor agonist. VAZCULEP (phenylephrine
194 hydrochloride) Injection, 10 mg/mL is a sterile, nonpyrogenic solution for intravenous use. It

195 must be diluted before administration as an intravenous bolus or continuous intravenous
196 infusion. The chemical name of phenylephrine hydrochloride is (-)-*m*-hydroxy- α -
197 [(methylamino)methyl]benzyl alcohol hydrochloride, and its structural formula is depicted
198 below:



199
200

201 Phenylephrine hydrochloride is soluble in water and ethanol, and insoluble in chloroform and
202 ethyl ether. VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL is sensitive to light.
203 Each mL contains: phenylephrine hydrochloride 10 mg, sodium chloride 3.5 mg, sodium citrate
204 dihydrate 4 mg, citric acid monohydrate 1 mg, and sodium metabisulfite 2 mg in water for
205 injection. The pH is adjusted with sodium hydroxide and/or hydrochloric acid if necessary. The
206 pH range is 3.5-5.5.

207 **12 CLINICAL PHARMACOLOGY**

208 **12.1 Mechanism of Action**

209 Phenylephrine hydrochloride is an α -1 adrenergic receptor agonist.

210 **12.2 Pharmacodynamics**

211 Interaction of phenylephrine with α 1-adrenergic receptors on vascular smooth muscle cells
212 causes activation of the cells and results in vasoconstriction. Following phenylephrine
213 hydrochloride intravenous administration, increases in systolic and diastolic blood pressures,
214 mean arterial blood pressure, and total peripheral vascular resistance are observed. The onset of
215 blood pressure increase following an intravenous bolus phenylephrine hydrochloride
216 administration is rapid, typically within minutes. As blood pressure increases following
217 intravenous administration, vagal activity also increases, resulting in reflex bradycardia.
218 Phenylephrine has activity on most vascular beds, including renal, pulmonary, and splanchnic
219 arteries.

220 **12.3 Pharmacokinetics**

221 Following an intravenous infusion of phenylephrine hydrochloride, the observed effective half-
222 life was approximately 5 minutes. The steady-state volume of distribution of approximately 340
223 L suggests a high distribution into organs and peripheral tissues. The average total serum
224 clearance is approximately 2100 mL/min. The observed phenylephrine plasma terminal
225 elimination half-life was 2.5 hours.

226 Phenylephrine is metabolized primarily by monoamine oxidase and sulfotransferase. After
227 intravenous administration of radiolabeled phenylephrine, approximately 80% of the total dose

228 was eliminated within first 12 h; and approximately 86% of the total dose was recovered in the
229 urine within 48 h. The excreted unchanged parent drug was 16% of the total dose in the urine at
230 48 h post intravenous administration. There are two major metabolites, with approximately 57
231 and 8% of the total dose excreted as *m*-hydroxymandelic acid and sulfate conjugates,
232 respectively. The metabolites are considered not pharmacologically active.

233 **13 NONCLINICAL TOXICOLOGY**

234 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

235 *Carcinogenesis*: Long-term animal studies that evaluated the carcinogenic potential of orally
236 administered phenylephrine hydrochloride in F344/N rats and B6C3F₁ mice were completed by
237 the National Toxicology Program using the dietary route of administration. There was no
238 evidence of carcinogenicity in mice administered approximately 270 mg/kg/day (131-times the
239 maximum recommended daily dose of < 10 mg/day) or rats administered approximately 50
240 mg/kg/day (48-times the maximum recommended daily dose of < 10 mg/day) based on body
241 surface area comparisons.

242 *Mutagenesis*: Phenylephrine hydrochloride tested negative in the in vitro bacterial reverse
243 mutation assay (*S.typhimurium* strains TA98, TA100, TA1535 and TA1537), the in vitro
244 chromosomal aberrations assay, the in vitro sister chromatid exchange assay, and the in vivo rat
245 micronucleus assay. Positive results were reported in only one of two replicates of the in vitro
246 mouse lymphoma assay.

247 *Impairment of Fertility*: Studies to evaluate the effect of phenylephrine on fertility have not been
248 conducted.

249 **14 CLINICAL STUDIES**

250 The evidence for the efficacy of VAZCULEP is derived from studies of phenylephrine
251 hydrochloride in the published literature. The literature support includes 16 studies evaluating
252 the use of intravenous phenylephrine to treat hypotension during anesthesia. The 16 studies
253 include 9 studies where phenylephrine was used in low-risk (ASA 1 and 2) pregnant women
254 undergoing neuraxial anesthesia during Cesarean delivery, 6 studies in non-obstetric surgery
255 under general anesthesia, and 1 study in non-obstetric surgery under combined general and
256 neuraxial anesthesia. Phenylephrine has been shown to raise systolic and mean blood pressure
257 when administered either as a bolus dose or by continuous infusion following the development of
258 hypotension during anesthesia.

259 **16 HOW SUPPLIED/STORAGE AND HANDLING**

260 VAZCULEP (phenylephrine hydrochloride) Injection, 10 mg/mL is supplied as follows:

NDC No.	Strength	How Supplied
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76014-004-30	10 mg/mL	1 mL vial; for single use (supplied in packages of 10)
76014-004-32	10 mg/mL	5 mL vial; Pharmacy Bulk Package (supplied in packages of 10)
76014-004-33	10 mg/mL	10 mL vial; Pharmacy Bulk Package (supplied as a single unit)

261 Vial stoppers are not manufactured with natural rubber latex. Store VAZCULEP (phenylephrine
262 hydrochloride) Injection, 10 mg/mL at 20°C to 25°C (68°F to 77°F), excursions permitted to
263 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from light. Store
264 in carton until time of use. The 1 mL vials are for single use only; the 5 and 10 mL vials are
265 pharmacy bulk packages.

266 The diluted solution should not be held for more than 4 hours at room temperature or for more
267 than 24 hours under refrigerated conditions. Discard any unused portion.

268 **17 PATIENT COUNSELING INFORMATION**

269 If applicable, inform patients, family member, or caregiver that certain medical conditions and
270 medications might influence how VAZCULEP (phenylephrine hydrochloride) Injection works.

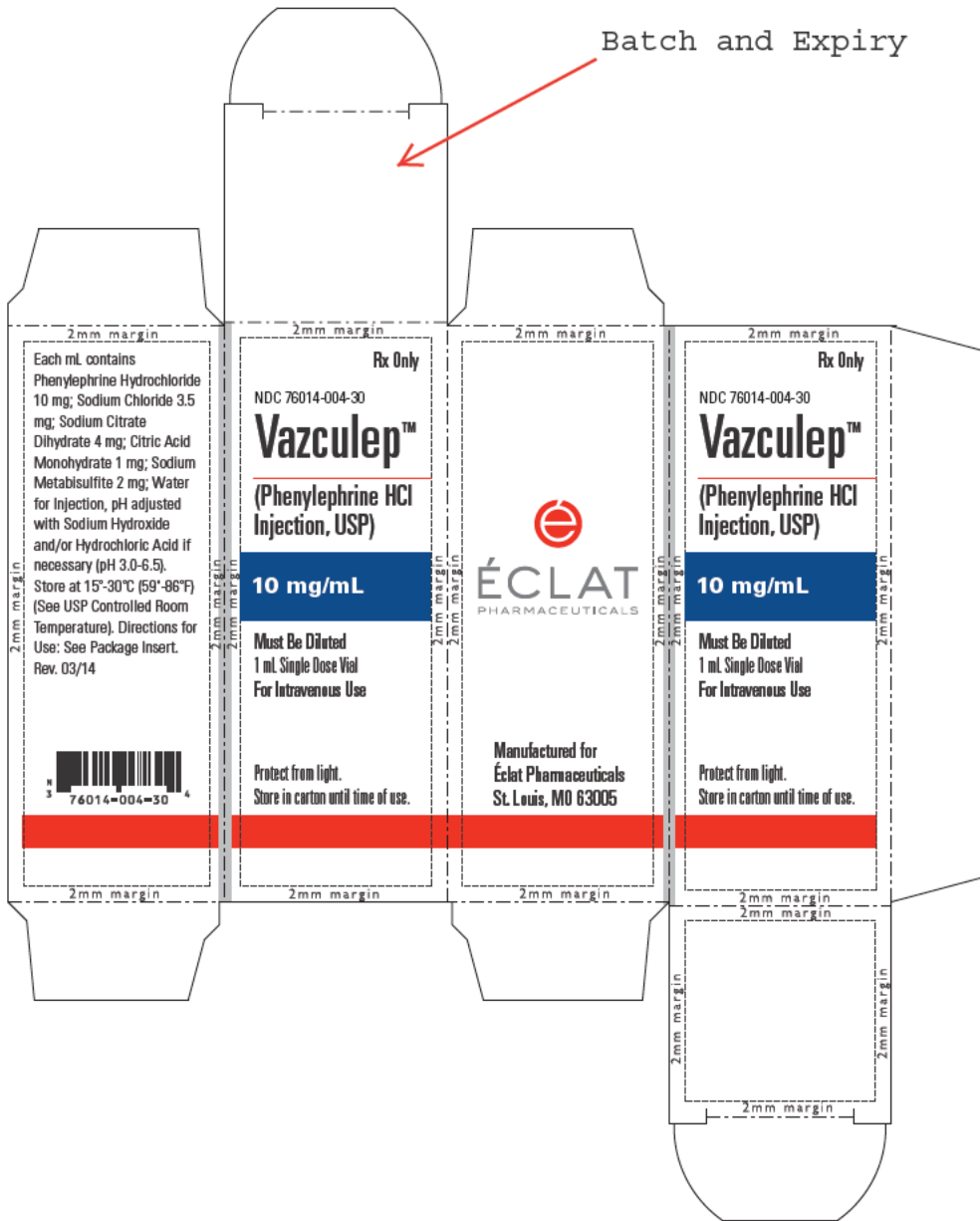
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272 Manufactured for:

273 Éclat Pharmaceuticals

274 Chesterfield, MO 63005 USA

Batch and Expiry



Each mL contains
Phenylephrine Hydrochloride
10 mg; Sodium Chloride 3.5
mg; Sodium Citrate
Dihydrate 4 mg; Citric Acid
Monohydrate 1 mg; Sodium
Metabisulfite 2 mg; Water
for Injection, pH adjusted
with Sodium Hydroxide
and/or Hydrochloric Acid if
necessary (pH 3.0-6.5).
Store at 15°-30°C (59°-86°F)
(See USP Controlled Room
Temperature). Directions for
Use: See Package Insert.
Rev. 03/14



Rx Only
NDC 76014-004-30
Vazculep™
(Phenylephrine HCl
Injection, USP)

10 mg/mL

**Must Be Diluted
1 mL Single Dose Vial
For Intravenous Use**

Protect from light.
Store in carton until time of use.



Manufactured for
Éclat Pharmaceuticals
St. Louis, MO 63005

Rx Only
NDC 76014-004-30
Vazculep™
(Phenylephrine HCl
Injection, USP)

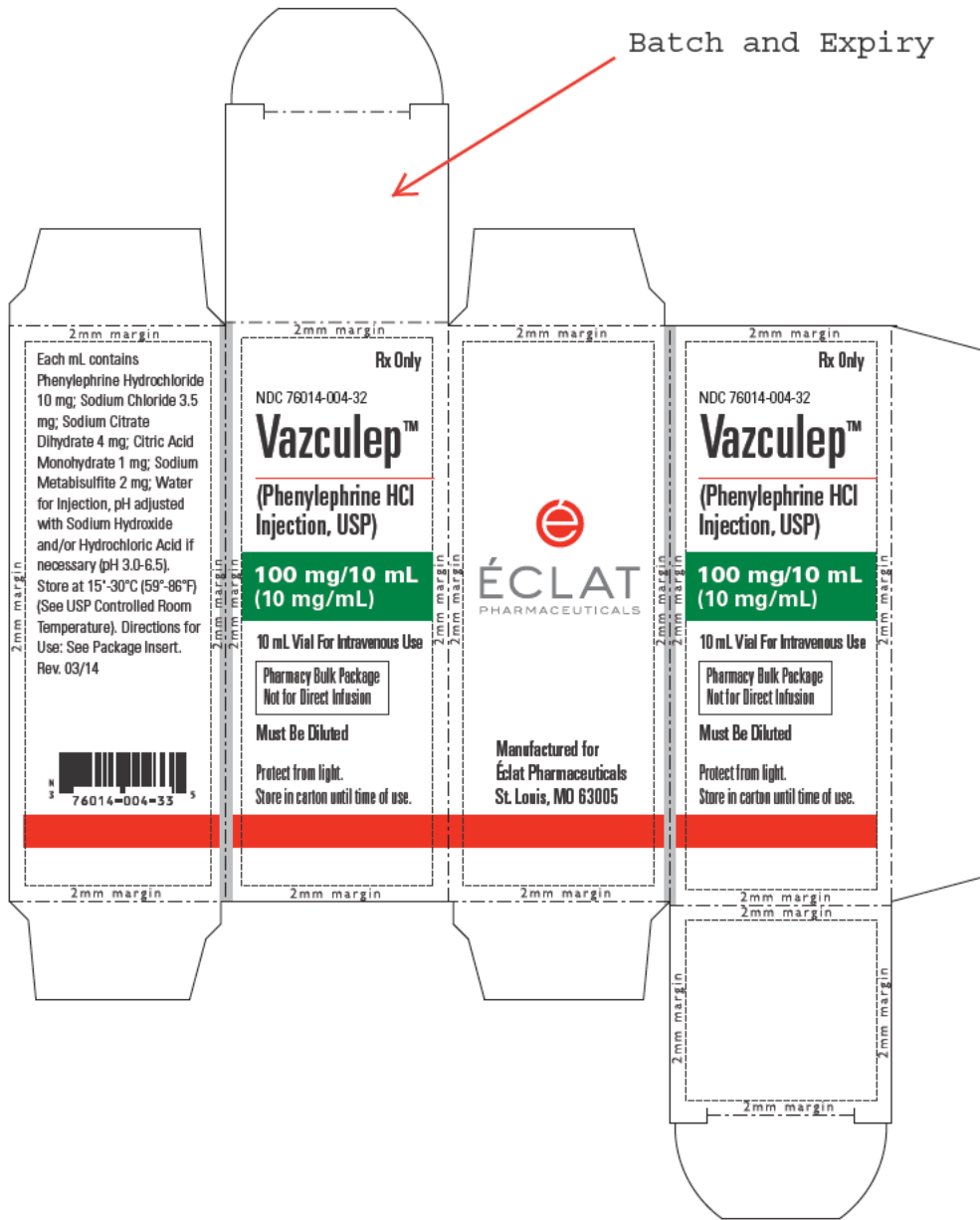
10 mg/mL

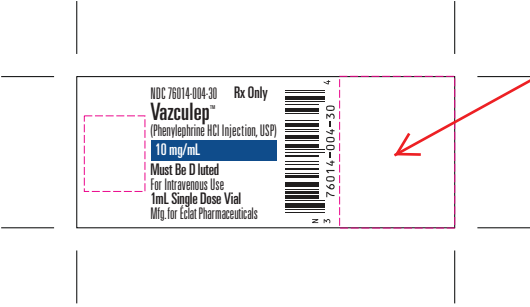
**Must Be Diluted
1 mL Single Dose Vial
For Intravenous Use**

Protect from light.
Store in carton until time of use.

Batch and Expiry

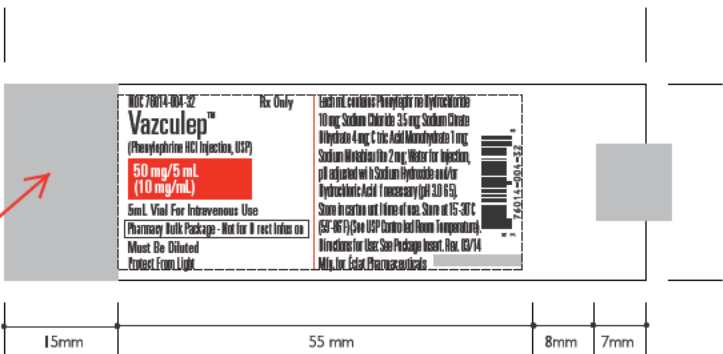
Rx Only





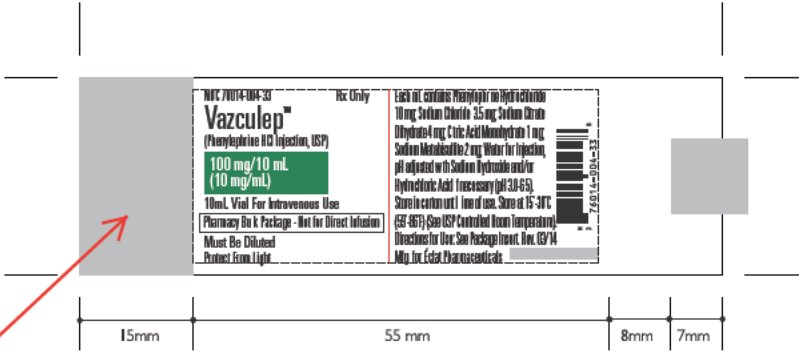
Batch and Expiry

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Batch and Expiry

Area reserved for (b) (4) security codes



Batch and Expiry

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/s/

RIGOBERTO A ROCA
06/27/2014