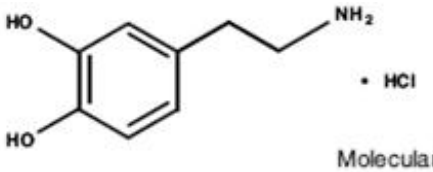
DOPAMINE HCL- dopamine hcl injection, solution
American Regent, Inc.

DOPamine HYDROCHLORIDE INJECTION, USP

Rx Only

DESCRIPTION

Dopamine, a sympathomimetic amine vasopressor, is the naturally occurring immediate precursor of norepinephrine. Dopamine hydrochloride is a white to off-white crystalline powder, which may have a slight odor of hydrochloric acid. It is freely soluble in water and soluble in alcohol. Dopamine HCl is sensitive to alkalies, iron salts, and oxidizing agents. Chemically it is designated as 4-(2-aminoethyl) pyrocatechol hydrochloride, and the structural formula is:



$C_8H_{11}NO_2 \cdot HCl$ Molecular Weight: 189.64

Dopamine Hydrochloride Injection is a clear, practically colorless, sterile, pyrogen-free, aqueous solution of dopamine HCl for intravenous infusion after dilution. Each mL contains either 40 mg, 80 mg, or 160 mg of dopamine hydrochloride (equivalent to 32.3 mg, 64.6 mg and 129.2 mg of dopamine base respectively) in water for injection, q.s. Each mL of all preparations contains the following: sodium metabisulfite 9 mg added as an antioxidant; citric acid, anhydrous 10 mg and sodium citrate, dihydrate 5 mg added as a buffer. The pH range (2.5 to 5.0) may be adjusted with additional citric acid and/or sodium citrate.

Dopamine must be diluted in an appropriate sterile parenteral solution (see **DOSAGE AND ADMINISTRATION** section).

CLINICAL PHARMACOLOGY

Dopamine is a natural catecholamine formed by the decarboxylation of 3,4-dihydroxyphenylalanine (DOPA). It is a precursor to norepinephrine in noradrenergic nerves and is also a neurotransmitter in certain areas of the central nervous system, especially in the nigrostriatal tract, and in a few peripheral sympathetic nerves.

Dopamine produces positive chronotropic and inotropic effects on the myocardium, resulting in increased heart rate and cardiac contractility. This is accomplished directly by exerting an agonist action on beta-adrenoceptors and indirectly by causing release of norepinephrine from storage sites in sympathetic nerve endings.

Dopamine's onset of action occurs within five minutes of intravenous administration, and with dopamine's plasma half-life of about two minutes, the duration of action is less than ten minutes. If monoamine oxidase (MAO) inhibitors are present, however, the duration may increase to one hour. The drug is widely distributed in the body but does not cross the blood-brain barrier to a significant extent. Dopamine is metabolized in the liver, kidney, and plasma by MAO and catechol-O-methyltransferase to the inactive compounds homovanillic acid (HVA) and 3,4-dihydroxyphenylacetic acid. About 25% of the dose is taken up into specialized neurosecretory vesicles (the adrenergic nerve terminals), where it is hydroxylated to form norepinephrine. It has been reported that about 80% of the drug is excreted in

the urine within 24 hours, primarily as HVA and its sulfate and glucuronide conjugates and as 3,4-dihydroxyphenylacetic acid. A very small portion is excreted unchanged.

The predominant effects of dopamine are dose-related, although it should be noted that actual response of an individual patient will largely depend on the clinical status of the patient at the time the drug is administered. At low rates of infusion (0.5 to 2 mcg/kg/min) dopamine causes vasodilation that is presumed to be due to a specific agonist action on dopamine receptors (distinct from alpha and beta adrenoceptors) in the renal, mesenteric, coronary, and intracerebral vascular beds. At these dopamine receptors, haloperidol is an antagonist. The vasodilation in these vascular beds is accompanied by increased glomerular filtration rate, renal blood flow, sodium excretion, and urine flow. Hypotension sometimes occurs. An increase in urinary output produced by dopamine is usually not associated with a decrease in osmolarity of the urine.

At intermediate rates of infusion (2 to 10 mcg/kg/min) dopamine acts to stimulate the $beta_1$-adrenoceptors, resulting in improved myocardial contractility, increased SA rate and enhanced impulse conduction in the heart. There is little, if any, stimulation of the $beta_2$-adrenoceptors (peripheral vasodilation). Dopamine causes less increase in myocardial oxygen consumption than isoproterenol, and its use is not usually associated with a tachyarrhythmia. Clinical studies indicate that it usually increases systolic and pulse pressure with either no effect or a slight increase in diastolic pressure. Blood flow to the peripheral vascular beds may decrease while mesenteric flow increases due to increased cardiac output. Total peripheral resistance (alpha effects) at low and intermediate doses is usually unchanged.

At higher rates of infusion (10 to 20 mcg/kg/min) there is some effect on alpha-adrenoceptors, with consequent vasoconstrictor effects and a rise in blood pressure. The vasoconstrictor effects are first seen in the skeletal muscle vascular beds, but with increasing doses they are also evident in the renal and mesenteric vessels. At very high rates of infusion (above 20 mcg/kg/min), stimulation of alpha-adrenoceptors predominates and vasoconstriction may compromise the circulation of the limbs and override the dopaminergic effects of dopamine, reversing renal dilation and natriuresis.

INDICATIONS AND USAGE

Dopamine HCl is indicated for the correction of hemodynamic imbalances present in the shock syndrome due to myocardial infarction, trauma, endotoxic septicemia, open-heart surgery, renal failure, and chronic cardiac decompensation as in congestive failure.

Patients most likely to respond adequately to dodpamine HCl are those in whom physiological parameters, such as urine flow, myocardial function, and blood pressure, have not undergone profound deterioration. Multiclinic trials indicate that the shorter the time interval between onset of signs and symptoms and initiation of therapy with volume correction and dopamine HCl, the better the prognosis. Where appropriate, blood volume restoration with a suitable plasma expander or whole blood should be accomplished or completed prior to administration of dopamine HCl.

Poor Perfusion of Vital Organs:

Urine flow appears to be one of the better diagnostic signs by which adequacy of vital organ perfusion can be monitored. Nevertheless, the physician should also observe the patient for signs of reversal of confusion or reversal of comatose condition. Loss of pallor, increase in toe temperature, and/or adequacy of nail bed capillary filling may also be used as indices of adequate dosage. Clinical studies have shown that when dopamine HCl is administered before urine flow has diminished to levels approximating 0.3 mL/minute, prognosis is more favorable. Nevertheless, in a number of oliguric or anuric patients, administration of dopamine HCl has resulted in an increase in urine flow which in some cases reached normal levels. Dopamine HCl may also increase urine flow in patients whose output is within normal limits and thus may be of value in reducing the degree of pre-existing fluid accumulation. It should be noted that at doses above those optimal for the individual patient, urine flow may decrease, necessitating reduction of dosage.

Low Cardiac Output:

Increased cardiac output is related to dopamine's direct inotropic effect on the myocardium. Increased cardiac output at low or moderate doses appears to be related to a favorable prognosis. Increase in cardiac output has been associated with either static or decreased systemic vascular resistance (SVR). Static or decreased SVR associated with low or moderate movements in cardiac output is believed to be a reflection of differential effects on specific vascular beds with increased resistance in peripheral beds (e.g., femoral) and concomitant decreases in mesenteric and renal vascular beds.

Redistribution of blood flow parallels these changes so that an increase in cardiac output is accompanied by an increase in mesenteric and renal blood flow. In many instances the renal fraction of the total cardiac output has been found to increase. Increase in cardiac output produced by dopamine is not associated with substantial decreases in systemic vascular resistance as may occur with isoproterenol.

Hypotension:

Hypotension due to inadequate cardiac output can be managed by administration of low to moderate doses of dopamine HCl, which have little effect on SVR. At high therapeutic doses, the alpha-adrenergic activity of dopamine becomes more prominent and thus may correct hypotension due to diminished SVR. As in the case of other circulatory decompensation states, prognosis is better in patients whose blood pressure and urine flow have not undergone profound deterioration. Therefore, it is suggested that the physician administer dopamine HCl as soon as a definite trend toward decreased systolic and diastolic pressure becomes evident.

CONTRAINDICATIONS

Dopamine HCl should not be used in patients with pheochromocytoma.

Dopamine HCl should not be administered to patients with uncorrected tachyarrhythmias or ventricular fibrillation.

WARNINGS

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

Do NOT add dopamine HCl to any alkaline diluent solution since the drug is inactivated in alkaline solution.

Patients who have been receiving MAO inhibitors prior to the administration of dopamine HCl will require substantially reduced dosage. See **Drug Interactions** below.

PRECAUTIONS

General:

1. Monitoring- Careful monitoring of the following indices is necessary during dopamine HCl infusion, as with any adrenergic agent: blood pressure, urine flow, and, when possible, cardiac output and pulmonary wedge pressure.

2. Hypovolemia- Prior to treatment with dopamine HCl, hypovolemia should be fully corrected, if possible, with either whole blood or plasma as indicated. Monitoring of central venous pressure of left ventricular filling pressure may be helpful in detecting and treating hypovolemia.

3. Hypoxia, Hypercapnia, Acidosis- These conditions which may also reduce the effectiveness and/or increase the incidence of adverse effects of dopamine, must be identified and corrected prior to, or concurrently with administration of dopamine HCl.

4. Decreased Pulse Pressure- If a disproportionate increase in diastolic pressure and a marked decrease in the pulse pressure are observed in patients receiving dopamine HCl, the rate of infusion should be decreased and the patient observed carefully for further evidence of predominant vasoconstrictor activity, unless such an effect is desired.

5. Ventricular Arrhythmias- If an increased number of ectopic beats are observed, the dose should be reduced if possible.

6. Hypotension- At lower infusion rates, if hypotension occurs, the infusion rate should be rapidly increased until adequate blood pressure is obtained. If hypotension persists, dopamine HCl should be discontinued and a more potent vasoconstrictor agent such as norepinephrine should be administered.

7. Extravasation - Dopamine HCl should be infused into a large vein whenever possible to prevent the possibility of extravasation into tissue adjacent to the infusion site. Extravasation may cause necrosis and sloughing of surrounding tissue. Large veins of the antecubital fossa are preferred to veins in the dorsum of the hand or ankle. Less suitable infusion sites should be used only if the patient's condition requires immediate attention. The physician should switch to more suitable sites as rapidly as possible. The infusion site should be continuously monitored for free flow.

8. Occlusive Vascular Disease- Patients with a history of occlusive vascular disease (for example, atheroscierosis, arterial embolism, and Raynaud's disease, cold injury, diabetic endarteritis, and Buergers disease) should be closely monitored for any changes in color or temperature of the skin in the extremities. If a change in skin color or temperature occurs and is thought to be the result of compromised circulation to the extremities, the benefits of continued dopamine HCl infusion should be weighed against the risk of possible necrosis. This condition may be reversed by either decreasing the rate or discontinuing the infusion.

IMPORTANT - *Antidote for Peripheral Ischemia* - To prevent sloughing and necrosis in ischemic areas, the area should be infiltrated as soon as possible with 10 to 15 mL of saline solution containing 5 to 10 mg of phentolamine mesylate, an adrenergic blocking agent. A syringe with a fine hypodermic needle should be used, and the solution liberally infiltrated throughout the ischemic area. Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours. Therefore, phentolamine should be given as soon as possible after the extravasation is noted.

9. Weaning- When discontinuing the infusion, it may be necessary to gradually decrease the dose of dopamine HCl while expanding blood volume with intravenous fluids, since sudden cessation may result in marked hypotension.

Drug Interactions:

1. Because dopamine is metabolized by monoamine oxidase (MAO), inhibition of this enzyme prolongs and potentiates the effect of dopamine. Patients who have been treated with ***MAO inhibitors*** within two to three weeks prior to the administration of dopamine HCl should receive initial doses of dopamine HCl no greater than one-tenth (1/10) of the usual dose.

2. Concurrent administration of dopamine HCl and ***diuretic agents*** may produce an additive or potentiating effect on urine flow.

3. ***Tricyclic antidepressants*** may potentiate the pressor response to adrenergic agents.

4. Cardiac effects of dopamine are antagonized by ***beta-adrenergic blocking agents***, such as propranolol and metroprolol. The peripheral vasoconstriction caused by high doses of dopamine HCl is antagonized

by ***alpha-adrenergic blocking agents***. Dopamine-induced renal and mesenteric vasodilation is not antagonized by either alpha- or beta-adrenergic blocking agents.

5. ***Haloperidol*** appears to have strong central antidopaminergic properties. Haloperidol and haloperidol-like drugs suppress the dopaminergic renal and mesenteric vasodilation induced at low rates of dopamine infusion.

6. ***Cyclopropane or halogenated hydrocarbon anesthetics*** increase cardiac autonomic irritability and may sensitize the myocardium to the action of certain intravenously administered catecholamines, such as dopamine. The interaction appears to be related both to pressor activity and to the beta-adrenergic stimulating properties of these catecholamines, and may produce ventricular arrhythmias. Therefore, EXTREME CAUTION should be exercised when administering dopamine HCl to patients receiving cyclopropane or halogenated hydrocarbon anesthetics. It has been reported that results of studies in animals indicated that dopamine-induced ventricular arrhythmias during anesthesia can be reversed by propranolol.

7. The concomitant use of vasopressors, vasoconstricting agents and some ***oxytocic drugs*** may result in severe persistent hypertension. See **Labor and Deliver**y below.

8. Administration of ***phenytoin*** to patients receiving dopamine HCl has been reported to lead to hypotension and bradycardia. It is suggested that in patients receiving dopamine HCl, alternatives to phenytoin should be used if anticonvulsant therapy is needed.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term animal studies have not been performed to evaluate carcinogenic potential of dopamine hydrochloride.

Dopamine hydrochloride at doses approaching maximal solubility shows no clear genotoxic potential in the Ames test. Although there was a reproducible dose-dependent increase in the number of revertant colonies with strains TA100 and TA98, both with and without metabolic activation, the small increase was considered inconclusive evidence of mutagenicity. In the L5178Y $TK^{+/-}$ mouse lymphoma assay, dopamine hydrochloride at the highest concentrations used of 750 mcg/mL without metabolic activation, and 3000 mcg/mL with activation, was toxic and associated with increases in mutant frequencies when compared to untreated and solvent controls; at the lower concentrations no increases over controls were noted.

No clear evidence of clastogenic potential was reported in the *in vivo* mouse or male rat bone marrow micronucleus test when the animals were treated intravenously with up to 224 mg/kg and 30 mg/kg of dopamine hydrochloride, respectively.

Pregnancy:

Teratogenic Effects:

Teratogenicity studies in rats and rabbits at dopamine HCl dosages up to 6 mg/kg/day intravenously during organogenesis produced no detectable teratogenic or embryotoxic effects, although maternal toxicity consisting of mortalities, decrease body weight gain, and pharmacotoxic signs were observed in rats. In a published study, dopamine HCl administered at 10 mg/kg subcutaneously for 30 days, markedly prolonged metestrus and increased mean pituitary and ovary weights in female rats. Similar administration to pregnant rats throughout gestation or for 5 days starting on gestation day 10 or 15 resulted in decreased body weight gains, increased mortalities and slight increases in cataract formation among the offspring. There are no adequate and well-controlled studies in pregnant women, and it is not known if dopamine HCl crosses the placental barrier. Dopamine HCl should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery:

In obstetrics, if vasopressor drugs are used to correct hypotension or are added to a local anesthetic solution, some oxytocic drugs may cause severe persistent hypertension and may even cause rupture of a cerebral blood vessel to occur during the postpartum period.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dopamine HCl is administered to a nursing mother.

Pediatric Use:

Safety and effectiveness in children have not been established. Dopamine HCl has been used in a limited number of pediatric patients, but such use has been inadequate to fully define proper dosage and limitations for use.

Geriatric Use:

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

ADVERSE REACTIONS

The following adverse reactions have been observed, but there are not enough data to support an estimate of their frequency.

Cardiovascular System
ventricular arrhythmia (at very high doses), atrial fibrillation, ectopic beats, tachycardia, anginal pain, palpitation, cardiac conduction abnormalities, widened QRS complex, bradycardia, hypotension, hypertension, vasoconstriction

Respiratory System
dyspnea

Gastrointestinal System
nausea, vomiting

Metabolic/Nutritional System
azotemia

Central Nervous System
headache, anxiety

Dermatological System
piloerection

Other
Gangrene of the extremities has occurred when high doses were administered for prolonged periods or in patients with occlusive vascular disease receiving low doses of dopamine HCl.

OVERDOSAGE

In case of accidental overdosage, as evidenced by excessive elevation of blood pressure, reduce rate of administration or temporarily discontinue dopamine HCl until patient’s condition stabilizes. Since dopamine's duration of action is quite short, no additional remedial measures are usually necessary. If these measures fail to stabilize the patient’s condition, use of the short-acting alpha-adrenergic

blocking agent phentolamine should be considered.

DOSAGE AND ADMINISTRATION

WARNING: This is a potent drug: It must be diluted before administration to the patient.

Dopamine Hydrochloride Injection, USP is administered (only after dilution) by intravenous infusion.

Suggested Dilution: Transfer contents of one or more ampuls or vials by aseptic technique to either 250 mL or 500 mL of one of the following sterile intravenous solutions:

1. Sodium Chloride Injection, USP
2. Dextrose (5%) Injection, USP
3. Dextrose (5%) and Sodium Chloride (0.9%) Injection, USP
4. 5% Dextrose in 0.45% Sodium Chloride Solution Injection, USP
5. Dextrose (5%) and Lactated Ringer's Solution Injection
6. Sodium Lactate Injection, USP (1/6 Molar)
7. Lactated Ringer's Injection, USP

Dopamine Hydrochloride Injection, USP has been found to be stable for a minimum of 24 hours after dilution in the sterile intravenous solutions listed above. However, as with all intravenous admixtures, dilution should be made just prior to administration.

Do NOT add Dopamine Hydrochloride to Sodium Bicarbonate Injection, USP or other alkaline intravenous solutions, since the drug is inactivated in alkaline solution.

Rate of Administration: Dopamine Hydrochloride Injection, USP, after dilution, is administered intravenously by infusion through a suitable intravenous catheter or needle. When administering Dopamine Hydrochloride (or any potent medication) by continuous intravenous infusion, it is advisable to use a precision volume control intravenous set. Each patient must be individually titrated to the desired hemodynamic or renal response to dopamine.

Administration rates greater than 50 mcg/kg/minute have safely been used in advanced circulatory decompensation states. If unnecessary fluid expansion is of concern, adjustment of drug concentration may be preferred over increasing the flow rate of a less concentrated dilution.

Suggested Regimen:

1. When appropriate, increase blood volume with whole blood or plasma until central venous pressure is 10 to 15 cm H_2O or pulmonary wedge pressure is 14 to 18 mm Hg.

2. Begin infusion of diluted solution at doses of 2 to 5 mcg/kg/minute of Dopamine Hydrochloride in patients who are likely to respond to modest increments of heart force and renal perfusion.

In more seriously ill patients, begin infusion of diluted solution at doses of 5 mcg/kg/minute of Dopamine Hydrochloride and increase gradually using 5 to 10 mcg/kg/minute increments up to 20 to 50 mcg/kg/minute as needed. If doses in excess of 50 mcg/kg/minute are required, it is advisable to check urine output frequently. Should urinary flow begin to decrease in the absence of hypotension, reduction of dopamine dosage should be considered. Multiclinic trials have shown that more than 50% of the patients have been satisfactorily maintained on doses of dopamine less than 20 mcg/kg/minute. In patients who do not respond to these doses with adequate arterial pressures or urine flow, additional increments of dopamine may be given in an effort to produce an appropriate arterial pressure and central perfusion.

3. Treatment of all patients requires constant evaluation of therapy in terms of the blood volume, augmentation of cardiac contractility, and distribution of peripheral perfusion. Dosage of dopamine should be adjusted according to the patient's response, with particular attention to diminution of established urine flow rate, increasing tachycardia or development of new dysrhythmias as indices for decreasing or temporarily suspending the dosage.

4. As with all potent intravenously administered drugs, care should be taken to control the rate of administration to avoid inadvertent administration of a bolus of drug.

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

HOW SUPPLIED

Dopamine HCl Injection, USP is available as follows:

Product No.	Dopamine HCl mg per volume fill	How Packaged
NDC 0517-1805-25	200 mg/5 mL Vial (40 mg/mL)	Packages of 25 vials (color-coded WHITE)
NDC 0517-1905-25	400 mg/5 mL Vial (80 mg/mL)	Packages of 25 vials (color-coded GREEN)
NDC 0517-1305-25	800 mg/5 mL Vial (160 mg/mL)	Packages of 25 vials (color-coded YELLOW)

Avoid contact with alkalies (including sodium bicarbonate), oxidizing agents or iron salts.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

NOTE - Do not use the injection if it is darker than slightly yellow or discolored in any other way.

WARNING: NOT FOR DIRECT INTRAVENOUS INJECTION, MUST BE DILUTED BEFORE USE.

INTRAVENOUS INFUSION ONLY.

The vial stopper is not made with natural rubber latex.

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

IN1805
Rev. 12/14
MG #8090

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 5 mL (40 mg/mL)

CONTAINER

NDC 0517-1805-25

DOPamine HCl
INJECTION, USP

200 mg/5 mL (40 mg/mL)

5 mL SINGLE DOSE VIAL

WARNING: NOT FOR DIRECT IV INJECTION
MUST BE DILUTED BEFORE USE
IV INFUSION ONLY

Rx Only

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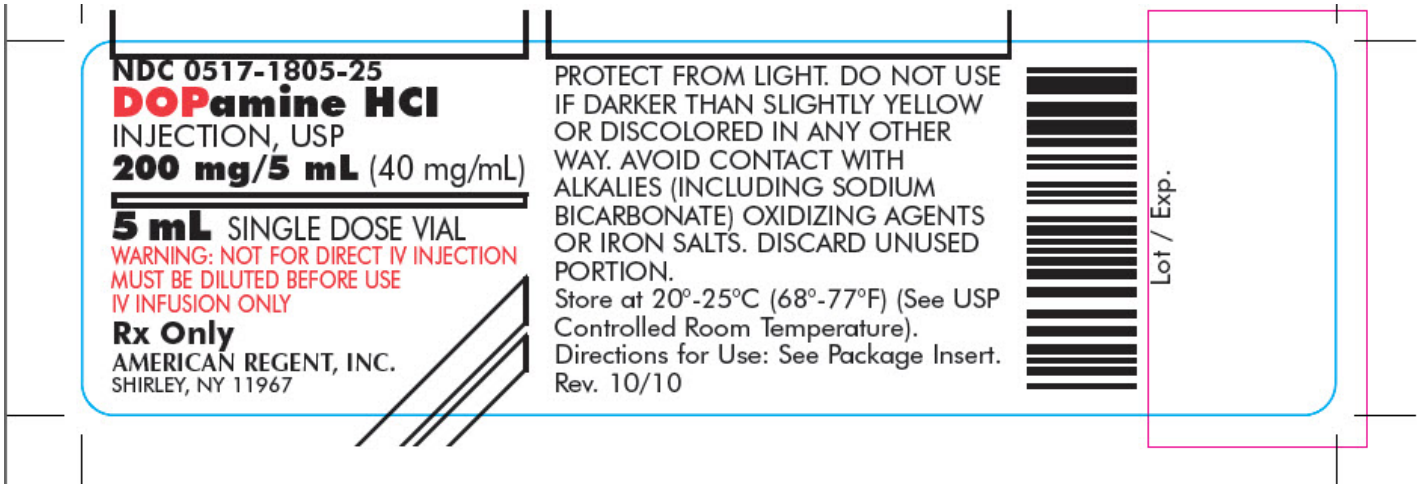
SHIRLEY, NY 11967



CARTON

DOPamine HCl
INJECTION, USP

200 mg/5 mL (40 mg/mL)

NDC 0517-1805-25

25 x 5 mL SINGLE DOSE VIALS

WARNING: NOT FOR DIRECT IV INJECTION. MUST BE DILUTED BEFORE USE.
IV INFUSION ONLY.

Rx Only

Each mL contains: Dopamine HCl 40 mg (equivalent to 32.3 mg Dopamine base), with Sodium Metabisulfite 9 mg as an antioxidant, Citric Acid (Anhydrous) 10 mg and Sodium Citrate (Dihydrate) 5 mg as a buffer, Water for Injection q.s. pH adjusted with Citric Acid and/or Sodium Citrate. Sterile, nonpyrogenic. PROTECT FROM LIGHT. RETAIN IN CARTON UNTIL TIME OF USE. DO NOT USE IF DARKER THAN SLIGHTLY YELLOW OR DISCOLORED IN ANY OTHER WAY. AVOID CONTACT WITH ALKALIES (INCLUDING SODIUM BICARBONATE), OXIDIZING AGENTS OR IRON SALTS.
DISCARD UNUSED PORTION. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).
Directions for Use: See Package Insert.

AMERICAN REGENT, INC.
SHIRLEY, NY 11967

Rev. 11/05

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 5 mL (80 mg/mL)

CONTAINER

NDC 0517-1905-25

DOPamine HCl
INJECTION, USP

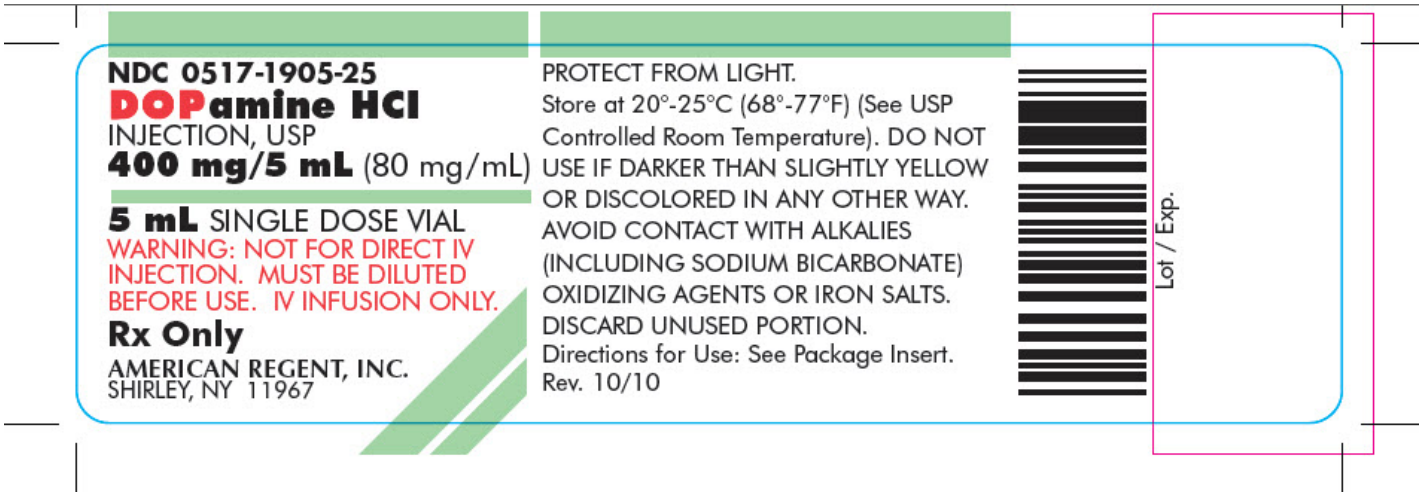
400 mg/5 mL (80 mg/mL)

5 mL SINGLE DOSE VIAL

WARNING: NOT FOR DIRECT IV INJECTION. MUST BE DILUTED BEFORE USE. IV INFUSION ONLY.

Rx Only

AMERICAN REGENT
SHIRLEY, NY 11967



CARTON

DOPamine HCl
INJECTION, USP

400 mg/5 mL (80 mg/mL)

NDC 0517-1905-25

25 x 5 mL SINGLE DOSE VIALS

WARNING: NOT FOR DIRECT IV INJECTION.MUST BE DILUTED BEFORE USE. IV INFUSION ONLY.

Rx Only

Each mL contains: Dopamine HCl 80 mg (equivalent to 64.6 mg Dopamine base), with Sodium Metabisulfite 9 mg as an antioxidant, Citric Acid (Anhydrous) 10 mg and Sodium Citrate (Dihydrate) 5 mg as a buffer, Water for Injection q.s. pH adjusted with Citric Acid and/or Sodium Citrate. Sterile, nonpyrogenic.PROTECT FROM LIGHT. RETAIN IN CARTON UNTIL TIME OF USE. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature). DO NOT USE IF DARKER THAN SLIGHTLY YELLOW OR DISCOLORED IN ANY OTHER WAY. AVOID CONTACT WITH ALKALIES (INCLUDING SODIUM BICARBONATE), OXIDIZING AGENTS OR IRON SALTS. DISCARD UNUSED PORTION.
Directions for Use: See Package Insert.

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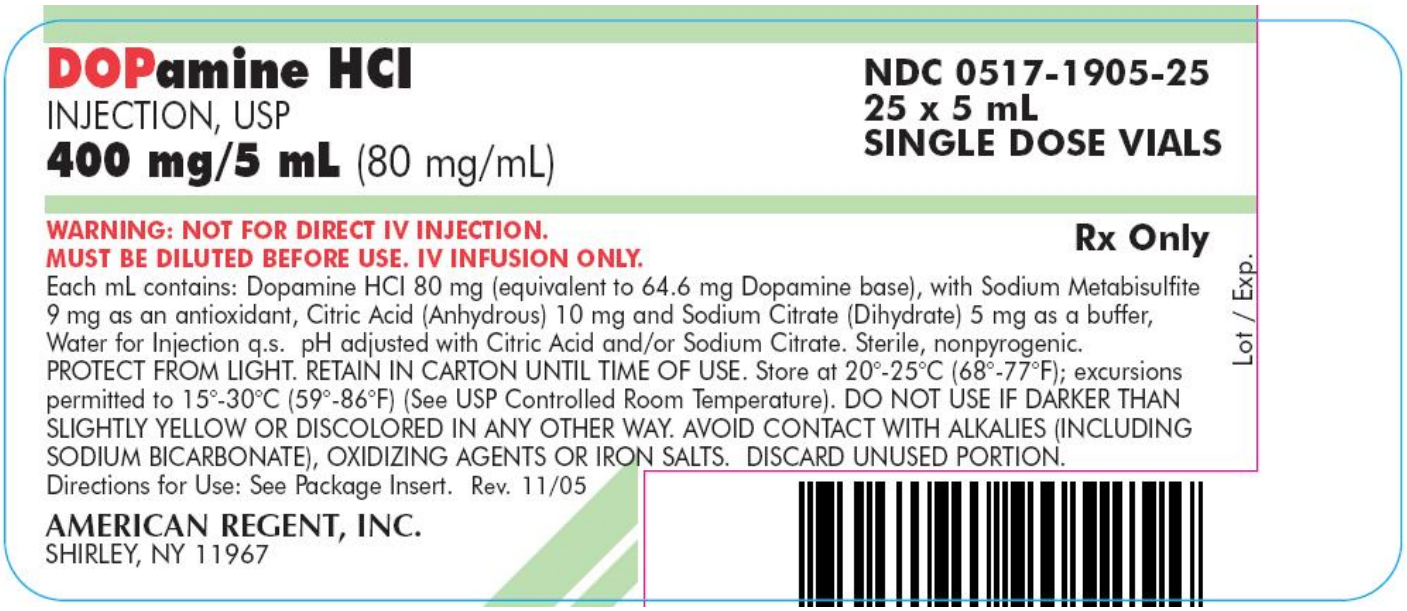
SHIRLEY, NY 11967

Rev. 11/05



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 5 mL (160 mg/mL)

CONTAINER

NDC 0517-1305-25

DOPamine HCl
INJECTION, USP

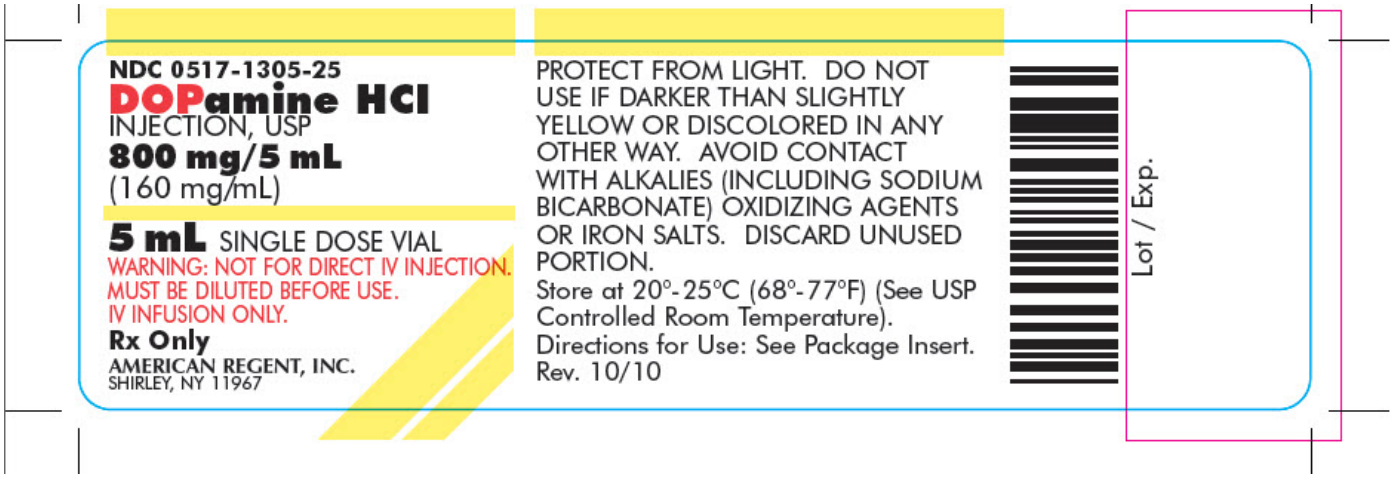
800 mg/5 mL (160 mg/mL)

5 mL SINGLE DOSE VIAL

WARNING: NOT FOR DIRECT IV INJECTION.
MUST BE DILUTED BEFORE USE.
IV INFUSION ONLY.

Rx Only

AMERICAN REGENT
SHIRLEY, NY 11967



CARTON

DOPamine HCl
INJECTION, USP

800 mg/5 mL (160 mg/mL)

NDC 0517-1305-25

25 x 5 mL SINGLE DOSE VIALS

WARNING: NOT FOR DIRECT IV INJECTION. MUST BE DILUTED BEFORE USE.

IV INFUSION ONLY.

Rx Only

Each mL contains: Dopamine HCl 160 mg (equivalent to 129.2 mg Dopamine base), with Sodium Metabisulfite 9 mg as an antioxidant, Citric Acid (Anhydrous) 10 mg and Sodium Citrate (Dihydrate) 5 mg as a buffer, Water for Injection q.s. pH adjusted with Citric Acid and/or Sodium Citrate. Sterile, nonpyrogenic. PROTECT FROM LIGHT. RETAIN IN CARTON UNTIL TIME OF USE. DO NOT USE IF DARKER THAN SLIGHTLY YELLOW OR DISCOLORED IN ANY OTHER WAY. AVOID CONTACT WITH ALKALIES (INCLUDING SODIUM BICARBONATE), OXIDIZING AGENTS OR IRON SALTS.
DISCARD UNUSED PORTION. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).
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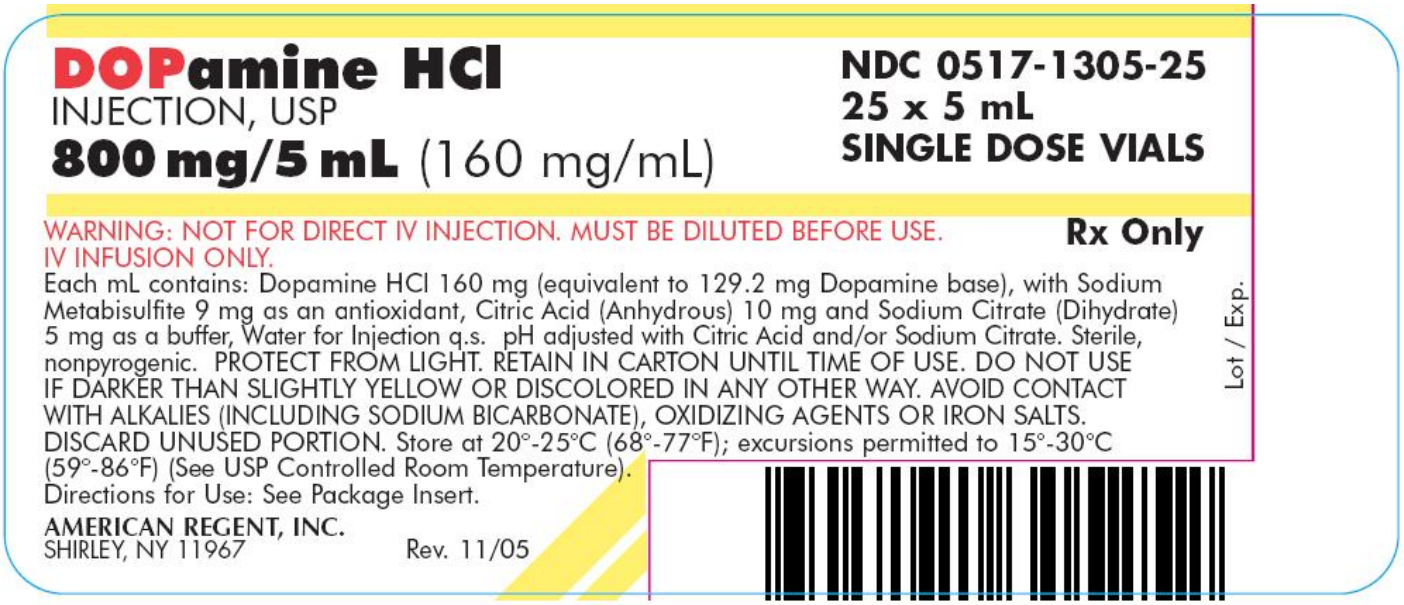
Rev. 11/05



DOPAMINE HCL

dopamine hcl injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-1305
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOPAMINE HYDROCHLORIDE (UNII: 7L3E358N9L) (DOPAMINE - UNII:VTD58H1Z2X)	DOPAMINE HYDROCHLORIDE	160 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	9 mg in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	10 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	5 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0517-1305-25	25 in 1 BOX		
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070826	09/30/1990	

DOPAMINE HCL

dopamine hcl injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-1805
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOPAMINE HYDROCHLORIDE (UNII: 7L3E358N9L) (DOPAMINE - UNII:VTD58H1Z2X)	DOPAMINE HYDROCHLORIDE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	9 mg in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	10 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	5 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0517-1805-25	25 in 1 BOX		
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070799	09/30/1990	

DOPAMINE HCL

dopamine hcl injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-1905

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOPAMINE HYDROCHLORIDE (UNII: 7L3E358N9L) (DOPAMINE - UNII:VTD58H1Z2X)	DOPAMINE HYDROCHLORIDE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	9 mg in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	10 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	5 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0517-1905-25	25 in 1 BOX		
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070820	09/30/1990	

Labeler - American Regent, Inc. (622781813)

Establishment

Name	Address	ID/FEI	Business Operations
Luitpold Pharmaceuticals, Inc.		002033710	ANALYSIS(0517-1305, 0517-1805, 0517-1905) , MANUFACTURE(0517-1305, 0517-1805, 0517-1905) , STERILIZE(0517-1305, 0517-1805, 0517-1905)

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