

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **DOPAMINE HYDROCHLORIDE IN DEXTROSE INJECTION** safely and effectively. See full prescribing information for **DOPAMINE HYDROCHLORIDE IN DEXTROSE INJECTION**.

DOPAMINE HYDROCHLORIDE IN DEXTROSE injection, for intravenous use

Initial U.S. Approval: 1974

INDICATIONS AND USAGE

Dopamine HCl in Dextrose Injection is a catecholamine indicated to improve hemodynamic status in patients in shock. (1)

DOSAGE AND ADMINISTRATION

- Correct hypovolemia, acidosis, and hypoxia prior to use. (2.1)
- Administer in a large vein with an infusion pump preferably in an intensive care setting. (2.1)
- Recommended starting dosage in adults and pediatric patients is 2 to 5 mcg/kg/minute as a continuous intravenous infusion. Titrate in 5 to 10 mcg/kg/minute increments based on hemodynamic response and tolerability, up to not more than 50 mcg/kg/minute. (2.2)
- See the Full Prescribing Information for important preparation instructions and drug incompatibilities. (2.3)

DOSAGE FORMS AND STRENGTHS

Following strengths of Dopamine Hydrochloride in 5% Dextrose Injection, USP, are supplied in LifeCare flexible single-dose plastic containers (each 100 mL contains 5 grams of hydrous dextrose in Water for Injection): (3)

- 1600 mcg/mL (250 and 500 mL)
- 3200 mcg/mL (250 mL)

CONTRAINDICATIONS

Patients with pheochromocytoma. (4)

WARNINGS AND PRECAUTIONS

- **Tissue ischemia:** Severe peripheral and visceral vasoconstriction can occur. Address hypovolemia prior to use, monitor extremities, and infuse into large vein. (5.1)
- **Cardiac arrhythmias:** Monitor closely. (5.2)
- **Hypotension after abrupt discontinuation:** Gradually reduce infusion rate while expanding blood volume with intravenous fluids. (5.3)
- **Severe hypersensitivity reactions due to sodium metabisulfite excipient:** May cause anaphylaxis including life-threatening or less severe asthmatic episodes in susceptible individuals. (5.4)

ADVERSE REACTIONS

The most common adverse reaction is localized vasoconstriction due to extravasation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer, Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- **Halogenated anesthetics:** Can sensitize the myocardium to the effects of dopamine and can produce ventricular arrhythmias and hypertension. (7)
- **MAO inhibitors:** Risk of severe hypertension. Reduce recommended Dopamine HCl in Dextrose Injection dosage. (7)
- **Tricyclic antidepressants:** Risk of hypertension. Monitor blood pressure. (7)
- **Vasopressors:** Risk of severe hypertension. Monitor blood pressure. (7)

See 17 for PATIENT COUNSELING INFORMATION.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dopamine Hydrochloride in Dextrose Injection is indicated to improve hemodynamic status in patients in distributive shock, or shock due to reduced cardiac output.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

Correct Hypovolemia, Acidosis, and Hypoxia

Address hypovolemia, acidosis, and hypoxia before initiating Dopamine HCl in Dextrose Injection. If patient does not respond to therapy, suspect occult hypovolemia. Acidosis may reduce the effectiveness of dopamine [see *Warnings and Precautions (5.1)*].

Administration

Dopamine HCl in Dextrose Injection is a premixed infusion solution that does not require dilution prior to intravenous administration. Administer Dopamine HCl in Dextrose Injection into a large vein [see *Warnings and Precautions (5.1)*] with the use of an infusion pump preferably in an intensive care setting.

Remove outer wrap (moisture and oxygen barrier) only when ready to administer the product. Discard product if outer wrap is damaged (e.g., tears or holes). Inspect Dopamine HCl in Dextrose Injection for particulate matter and discoloration prior to administration (the solution is clear to slightly yellow). Do not administer if the solution is darker than slightly yellow or the container is damaged.

Use higher concentration premixed solutions (e.g., 3200 mcg/mL or 1600 mcg/mL strengths) in patients requiring fluid restriction.

Discontinuation

When discontinuing Dopamine HCl in Dextrose Injection, gradually reduce the infusion rate while expanding blood volume with intravenous fluids [see *Warnings and Precautions (5.3)*].

2.2 Recommended Dosage

The recommended starting dosage in adults and pediatric patients is 2 to 5 mcg/kg/minute as a continuous intravenous infusion [see *Dosage and Administration (2.3)*]. Titrate the infusion rate in 5 to 10 mcg/kg/minute increments based on hemodynamic response and tolerability, up to but not more than 50 mcg/kg/minute.

Infusion rates may be calculated using the following formula:

$$\text{Infusion Rate (mL/hour)} = \frac{[\text{Dose (mcg/kg/minute)} \times \text{Weight (kg)} \times 60 \text{ (minutes/hour)}]}{\text{Concentration (mcg/mL)}}$$

Example calculations for infusion rates are as follows:

Example 1: for a 60 kg person at the recommended initial dose of 2 mcg/kg/minute using a 1600 mcg/mL concentration, the infusion rate would be as follows:

$$\text{Infusion Rate (mL/hour)} = \frac{[2 \text{ (mcg/kg/minute)} \times 60 \text{ (kg)} \times 60 \text{ (minutes/hour)}]}{1600 \text{ (mcg/mL)}} = 4.5 \text{ (mL/hour)}$$

Example 2: for a 70 kg person at a dose of 5 mcg/kg/minute using a 3,200 mcg/mL concentration, the infusion rate would be as follows:

$$\text{Infusion Rate (mL/hour)} = \frac{[5 \text{ (mcg/kg/minute)} \times 70 \text{ (kg)} \times 60 \text{ (minutes/hour)}]}{3200 \text{ (mcg/mL)}} = 6.56 \text{ (mL/hour)}$$

2.3 Drug Incompatibilities

Dopamine HCl in Dextrose Injection is incompatible with the following products; therefore, avoid simultaneous administration (through the same infusion set):

- Sodium bicarbonate or other alkalinizing substances, because dopamine is inactivated in alkaline solution.
- Blood, because of the risk of pseudoagglutination of red cells
- Iron salts

Do not add additional medications in the premixed infusion solution.

3 DOSAGE FORMS AND STRENGTHS

The following strengths of Dopamine Hydrochloride in 5% Dextrose Injection, USP, are supplied in LifeCare flexible single-dose plastic containers (the solutions are clear to slightly yellow in appearance):

- 1600 mcg/mL (250 or 500 mL)
- 3200 mcg/mL (250 mL)

Each 100 mL contains 5 grams of hydrous dextrose in Water for Injection.

4 CONTRAINDICATIONS

Dopamine is contraindicated in patients with pheochromocytoma.

5 WARNINGS AND PRECAUTIONS

5.1 Tissue Ischemia

Administration of dopamine to patients who are hypotensive from hypovolemia can result in severe peripheral and visceral vasoconstriction, decreased renal perfusion and hypouresis, tissue hypoxia, lactic acidosis, and poor systemic blood flow despite “normal” blood pressure. Address hypovolemia prior to initiating Dopamine HCl in Dextrose Injection [see *Dosage and Administration (2.2)*].

Gangrene of the extremities has occurred in patients with occlusive vascular disease or who received prolonged or high dose infusions. Monitor for changes to the skin of the extremities in susceptible patients.

Extravasation of Dopamine HCl in Dextrose Injection may cause necrosis and sloughing of surrounding tissue. To reduce the risk of extravasation, infuse into a large vein [see *Dosage and Administration (2.1)*], check the infusion site frequently for free flow, and monitor for signs of extravasation.

Emergency Treatment of Extravasation

To prevent sloughing and necrosis in areas in which extravasation has occurred, infiltrate the ischemic area as soon as possible, using a syringe with a fine hypodermic needle with:

- 5 to 10 mg of phentolamine mesylate in 10 to 15 mL of 0.9% Sodium Chloride Injection in adults
- 0.1 to 0.2 mg/kg of phentolamine mesylate up to a maximum of 10 mg per dose in pediatric patients.

Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours.

5.2 Cardiac Arrhythmias

Dopamine may cause arrhythmias. Monitor patients with arrhythmias and treat appropriately.

5.3 Hypotension after Abrupt Discontinuation

Sudden cessation of the infusion rate may result in marked hypotension. Gradually reduce the infusion rate while expanding blood volume with intravenous fluids.

5.4 Severe Hypersensitivity Reactions due to Sodium Metabisulfite Excipient

Dopamine HCl in Dextrose Injection, 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 non-asthmatic people.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Tissue Ischemia [*see Warnings and Precautions (5.1)*]
- Cardiac Arrhythmias [*see Warnings and Precautions (5.2)*]
- Hypotension [*see Warnings and Precautions (5.3)*]
- Severe Hypersensitivity Reactions [*see Warnings and Precautions (5.4)*]

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

Cardiac Disorders: anginal pain, palpitation

Gastrointestinal Disorders: nausea, vomiting

Metabolism and Nutrition Disorders: azotemia

Nervous System Disorders: headache, anxiety

Respiratory Disorders: dyspnea

Skin and Subcutaneous Tissue Disorders: piloerection

Vascular Disorders: hypertension

7 DRUG INTERACTIONS

See Table 1 for clinically significant drug interactions with dopamine.

Table 1: Clinically Significant Drug Interactions with Dopamine

Halogenated Anesthetics	
<i>Clinical Impact:</i>	Concomitant use may increase cardiac autonomic irritability and can sensitize the myocardium to the action of dopamine which may lead to ventricular arrhythmias and hypertension.
<i>Intervention:</i>	Monitor cardiac rhythm.
<i>Examples:</i>	desflurane, enflurane, isoflurane, and sevoflurane.
MAO Inhibitors	
<i>Clinical Impact:</i>	Because dopamine is metabolized by monoamine oxidase (MAO), inhibition of this enzyme prolongs and potentiates the effect of dopamine which may result in severe hypertension and cardiac arrhythmia.
<i>Intervention:</i>	Reduce the recommended starting dosage to no greater than one-tenth (1/10) of the recommended dose in patients who have been treated with MAO inhibitors within two to three weeks prior to the administration of Dopamine HCl in Dextrose Injection.
<i>Examples:</i>	isocarboxazid, phenelzine, tranylcypromine, rasagiline, selegiline, linezolid.
Tricyclic Antidepressants	
<i>Clinical Impact:</i>	Concomitant use may potentiate the cardiovascular effects of dopamine (e.g., hypertension).
<i>Intervention:</i>	Monitor blood pressure.
<i>Examples:</i>	amitriptyline, desipramine, doxepin, imipramine, nortriptyline.
Vasopressors	
<i>Clinical Impact:</i>	Concomitant use may result in severe hypertension.
<i>Intervention:</i>	Monitor blood pressure.
<i>Examples:</i>	norepinephrine, epinephrine, oxytocin.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no human data with dopamine use in pregnant women. There are risks to the mother and fetus from hypotension associated with shock, which can be fatal if left untreated (*see Clinical Considerations*). In animal reproduction studies, adverse developmental outcomes were observed with intravenous dopamine HCl administration in pregnant rats during organogenesis at dosages, on a mcg/m² basis, of one-third the human starting dosage of 2 mcg/kg/minute (90 mcg/m²/minute).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies carry some risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Hypotension associated with distributive shock, or shock due to reduced cardiac output are medical emergencies in pregnancy which can be fatal if left untreated. Delaying treatment in pregnant women with hypotension associated with distributive shock, or shock due to reduced cardiac output may increase the risk of

maternal and fetal morbidity and mortality. Life-sustaining therapy for the pregnant woman should not be withheld due to potential concerns regarding the effects of dopamine on the fetus.

Labor or Delivery

Vasopressor drugs, including dopamine, may cause severe maternal hypertension when used concomitantly with some oxytocic drugs [see *Drug Interactions (7)*].

Data

Animal Data

Animal reproduction studies in rats and rabbits at dopamine HCl dosages up to 6 mg/kg/day intravenously (on a mcg/m² basis, one-third and two-thirds, respectively, the human starting dosage of 2 mcg/kg/minute) during organogenesis produced no detectable teratogenic or embryotoxic effects, although maternal toxicity consisting of mortalities, decreased body weight gain, and pharmacotoxic signs were observed in rats. In a published study, administration of 10 mg/kg/day dopamine HCl (on a mcg/m² basis, two-thirds the human starting dosage of 2 mcg/kg/minute) to pregnant rats throughout gestation or for 5 days starting on gestation day 10 or 15 resulted in decreased body weight gain, increased mortality, and slight increase in cataract formation among the offspring.

8.2 Lactation

Risk Summary

There are no data regarding the presence of dopamine in human milk, the effects of dopamine on the breastfed infant, or the effects of the drug on milk production.

8.4 Pediatric Use

Dopamine HCl infusions have been used in pediatric patients from birth through adolescence. Most reports in pediatric patients describe dosing that is similar (on a mcg/kg/minute basis) to that used in adults [see *Dosage and Administration (2.2)*]. Except for vasoconstrictive effects caused by inadvertent infusion of dopamine into the umbilical artery, adverse reactions unique to pediatric patients have not been identified, nor have adverse reactions identified in adults been found to be more common in pediatric patients.

8.5 Geriatric Use

Clinical studies of dopamine 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 start at the low end of the dosing range, reflecting the frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE

Manifestations of overdose include excessive blood pressure elevation.

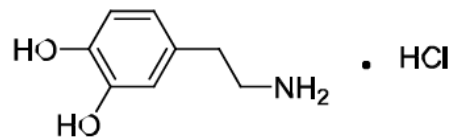
In the case of accidental overdose, reduce rate of Dopamine HCl in Dextrose Injection infusion, or temporarily discontinue the Dopamine HCl in Dextrose Injection infusion until the overdose related adverse reactions resolves. Since dopamine's duration of action is short, no additional remedial measures are usually necessary. If these measures fail to resolve the overdose related adverse reactions, consider using an alpha-adrenergic blocking agent (e.g., phentolamine).

11 DESCRIPTION

Dopamine Hydrochloride in 5% Dextrose Injection, USP is a sterile, nonpyrogenic, premixed solution of dopamine hydrochloride in 5% dextrose injection for intravenous infusion.

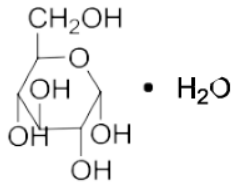
Each 100 mL contains 160 mg (1600 mcg/mL) or 320 mg (3200 mcg/mL) of dopamine HCl; 5 grams of hydrous dextrose, in Water for Injection, and 50 mg of sodium metabisulfite (a stabilizer); pH = 3.8 (2.5 to 4.5), and the following osmolar concentrations: 269, or 286 mOsmol/liter, respectively. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment.

Dopamine HCl is chemically designated 3, 4-dihydroxyphenethylamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$), a white crystalline powder freely soluble in water. Dopamine HCl has a molecular weight of 189.64 and it has the following structural formula:



Dopamine (also referred to as 3-hydroxytyramine) is a naturally occurring endogenous catecholamine.

Dextrose, USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. The molecular weight of dextrose (D-glucose) monohydrate is 198.17 and it has the following structural formula:



Water for Injection, USP is chemically designated H_2O .

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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 elicits its pharmacological action by activating dopamine D1 and D2 receptors, beta-1 receptors and alpha-1 receptors. The activation of different receptors leading to its effects are dependent on dopamine dose.

12.2 Pharmacodynamics

Dopamine's onset of action occurs within five minutes of intravenous administration and the duration of action is less than about ten minutes. Dopamine effects are dosage-dependent.

- At <5 mcg/kg/minute, dopamine HCl activates dopamine D1 and D2 receptors in the renal, mesenteric, and coronary vasculature causing vasodilation.

- At 5 to 10 mcg/kg/minute, dopamine HCl activates beta-1 receptors enhancing heart rate and contractility.
- At >10 mcg/kg/minute, dopamine HCl activates alpha-1 receptors causing vasoconstriction and increased blood pressure

12.3 Pharmacokinetics

Distribution

Following intravenous administration, dopamine is widely distributed in the body but does not cross the blood-brain barrier to a significant extent.

Elimination

The half-life of dopamine in adults is less than 2 minutes.

Metabolism

About 75% of dopamine is metabolized by monoamine oxidase (MAO) and catechol O-methyl transferase (COMT) in the liver, kidney, and plasma to the inactive compounds homovanillic acid (HVA) and 3,4-dihydroxyphenylacetic acid, and about 25% is metabolized to norepinephrine in the adrenergic nerve terminals.

Excretion

About 80% of dopamine is renally excreted as inactive metabolites within 24 hours. Dopamine is stored in vesicles or diffused back into the plasma.

Specific Populations

Pediatric Patients

The reported clearance rate of dopamine in critically ill infants and pediatric patients ranged from 46 to 168 mL/kg/minute, with the higher values seen in the younger patients. The reported apparent volume of distribution in neonates was 0.6 to 4 L/kg, leading to an elimination half-life of 5 to 11 minutes.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

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

Mutagenesis

Dopamine HCl at doses approaching maximal solubility showed 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 HCl 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 HCl, respectively.

16 HOW SUPPLIED/STORAGE AND HANDLING

Dopamine Hydrochloride in 5% Dextrose Injection, USP, is supplied in 250 and 500 mL LifeCare flexible single-dose plastic containers (the solutions are clear to slightly yellow in appearance) as follows. Each 100 mL contains 5 grams of hydrous dextrose in Water for Injection.

Unit of Sale	Total Strength/Total Volume (Concentration)
NDC 0409-7809-22 12 in a case	400 mg/250 mL (1600 mcg/mL)
NDC 0409-7809-24 12 in a case	800 mg/500 mL (1600 mcg/mL)
NDC 0409-7810-22 12 in a case	800 mg/250 mL (3200 mcg/mL)

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. Discard unused portion.

17 PATIENT COUNSELING INFORMATION

Risk of Tissue Damage

Advise the patient, family, or caregiver to report signs of extravasation urgently [see *Warnings and Precautions (5.1)*].

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