EPINEPHRINE- epinephrine injection, solution
Baxter Healthcare Corporation

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPINEPHRINE IN SODIUM CHLORIDE INJECTION safely and effectively. See full prescribing information for EPINEPHRINE IN SODIUM CHLORIDE INJECTION.
EPINEPHRINE IN SODIUM CHLORIDE injection, for intravenous use
Initial U.S. Approval: 1939

INDICATIONS AND USAGE

Epinephrine in 0.9% Sodium Chloride Injection is a non-selective alpha- and beta-adrenergic agonist indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock. (1.1)

DOSAGE AND ADMINISTRATION

Hypotension associated with septic shock:

- Infuse Epinephrine in 0.9% Sodium Chloride Injection into a large vein. (2.2)
- Intravenous infusion rate of 0.05 mcg/kg/min to 2 mcg/kg/min, titrated to achieve desired mean arterial pressure. (2.2)
- Wean gradually. (2.2)

DOSAGE FORMS AND STRENGTHS

Injection: 16 mg Epinephrine in 250 mL 0.9% Sodium Chloride Injection (64 mcg/mL), in single-dose VIAFLO container. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Monitor patient for acute severe hypertension. (5.1)
- Potential for pulmonary edema, which may be fatal. (5.2)
- May induce potentially serious cardiac arrhythmias and myocardial ischemia, particularly in patients with underlying heart disease. (5.3)
- Avoid extravasation into tissues, which can cause local necrosis. (5.4)
- Potential for oliguria or renal impairment. (5.5)
- Presence of sulfite in this product should not deter use for hypotension associated with septic shock (5.6)

ADVERSE REACTIONS

Most common adverse reactions to systemically administered Epinephrine in 0.9% Sodium Chloride Injection are headache; anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; diaphoresis; nausea/vomiting; and/or respiratory difficulties. Arrhythmias, including fatal ventricular fibrillation, rapid rises in blood pressure producing cerebral hemorrhage, and angina have occurred. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare Corporation at 1-877-725-2747, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Drugs that counter the pressor effects of Epinephrine in 0.9% Sodium Chloride Injection include alpha blockers, vasodilators such as nitrates, diuretics, antihypertensives, and ergot alkaloids. (7.1)
- Drugs that potentiate the effects of Epinephrine in 0.9% Sodium Chloride Injection include sympathomimetics, beta blockers, tricyclic antidepressants, MAO inhibitors, COMT inhibitors, clonidine, doxapram, oxytocin, levothyroxine sodium, and certain antihistamines. (7.2)
- Drugs that increase the arrhythmogenic potential of Epinephrine in 0.9% Sodium Chloride Injection include beta blockers, cyclopropane and halogenated hydrocarbon anesthetics, quinidine, antihistamines, exogenous thyroid hormones, diuretics, and cardiac glycosides. Observe for development of cardiac arrhythmias. (7.3)
- Potassium-depleting drugs, including corticosteroids, diuretics, and theophylline, potentiate the hypokalemic effects of Epinephrine in 0.9% Sodium Chloride Injection. (7.4)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Epinephrine in 0.9% Sodium Chloride Injection may cause fetal harm. (8.1)
- Elderly patients and pregnant women may be at greater risk of developing adverse reactions when Epinephrine in 0.9% Sodium Chloride Injection is administered parenterally. (8.1, 8.5)

Revised: 7/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Hypotension associated with Septic Shock

Epinephrine in 0.9% Sodium Chloride Injection is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

2 DOSAGE AND ADMINISTRATION

2.1 General Considerations

Epinephrine in 0.9% Sodium Chloride Injection is a ready to administer product that requires no further dilution prior to infusion. Inspect visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is colored or cloudy, or if it contains particulate matter. Discard all unused drug.

2.2 Hypotension associated with Septic Shock

Whenever possible, give infusions of Epinephrine in 0.9% Sodium Chloride Injection into a large vein. Avoid using a catheter tie-in technique, because the obstruction to blood flow around the tubing may cause stasis and increased local concentration of the drug. Avoid the veins of the leg in elderly patients or in those suffering from occlusive vascular diseases.

To provide hemodynamic support in septic shock associated hypotension in adult patients, the suggested dosing infusion rate of intravenously administered Epinephrine in 0.9% Sodium Chloride Injection is 0.05 mcg/kg/min to 2 mcg/kg/min and is titrated to achieve a desired mean arterial pressure (MAP). The dosage may be adjusted periodically, such as every 10 to 15 minutes, in increments of 0.05 mcg/kg/min to 0.2 mcg/kg/min, to achieve the desired blood pressure goal. The ideal body weight (IBW) should be used as the weight parameter for dosing epinephrine in adult patients with septic shock associated hypotension.

After hemodynamic stabilization, wean incrementally over time, such as by decreasing doses of Epinephrine in 0.9% Sodium Chloride Injection every 30 minutes over a 12 to 24 hour period.

3 DOSAGE FORMS AND STRENGTHS

Injection: 16 mg Epinephrine in 250 mL 0.9% Sodium Chloride Injection (64 mcg/mL), is a clear, colorless, premixed solution in a ready to use, single-dose VIAFLO container.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hypertension

Because individual response to epinephrine may vary significantly, monitor blood pressure frequently and titrate to avoid excessive increases in blood pressure.

Patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types may experience severe, prolonged hypertension when given epinephrine.

5.2 Pulmonary Edema

Epinephrine increases cardiac output and causes peripheral vasoconstriction, which may result in pulmonary edema.

5.3 Cardiac Arrhythmias and Ischemia

Epinephrine may induce cardiac arrhythmias and myocardial ischemia in patients, especially patients with coronary artery disease, or cardiomyopathy *[see Adverse Reactions and Drug Interactions (7.3)]*.

5.4 Extravasation and Tissue Necrosis with Intravenous Infusion

Avoid extravasation of epinephrine into the tissues, to prevent local necrosis. When Epinephrine in 0.9% Sodium Chloride Injection is administered intravenously, check the infusion site frequently for free flow. Blanching along the course of the infused vein, sometimes without obvious extravasation, may be attributed to vasa vasorum constriction with increased permeability of the vein wall, permitting some leakage. This also may progress on rare occasions to a superficial slough. Hence, if blanching occurs, consider changing the infusion site at intervals to allow the effects of local vasoconstriction to subside.

There is potential for gangrene in a lower extremity when infusions of catecholamine are given in an ankle vein.

Antidote for Extravasation Ischemia: To prevent sloughing and necrosis in areas in which extravasation has taken place, infiltrate the area with 10 mL to 15 mL of saline solution containing from 5 mg to 10 mg of phentolamine, an adrenergic blocking agent. Use a syringe with a fine hypodermic needle, with the solution being infiltrated liberally throughout the area, which is easily identified by its cold, hard, and pallid appearance. Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours.

5.5 Renal Impairment

Epinephrine constricts renal blood vessels, which may result in oliguria or renal impairment.

5.6 Allergic Reactions associated with Sulfite

Epinephrine in 0.9% Sodium Chloride Injection contains sodium metabisulfite which may cause mild to severe allergic reactions including anaphylaxis or asthmatic episodes, particularly in patients with a history of allergies. The presence of sodium metabisulfite in this product should not preclude its use for the treatment of hypotension associated with septic shock even if the patient is sulfite-sensitive, as the alternatives to using epinephrine in a life-threatening situation may not be satisfactory. In susceptible patients, consider using a formulation of epinephrine or another vasoconstrictor that does not contain sodium metabisulfite.

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in labeling:

- Hypertension *[see Warnings and Precautions (5.1)]*
- Pulmonary Edema *[see Warnings and Precautions (5.2)]*
- Cardiac Arrhythmias and Ischemia *[see Warnings and Precautions (5.3)]*
- Extravasation and Tissue Necrosis with Intravenous Infusion *[see Warnings and Precautions (5.4)]*
- Renal Impairment *[see Warnings and Precautions (5.5)]*
- Allergic Reactions associated with Sulfite *[see Warnings and Precautions (5.6)]*

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

Cardiovascular disorders: tachycardia, supraventricular tachycardia, ventricular arrhythmias (including fatal ventricular fibrillation), stress cardiomyopathy, myocardial ischemia, myocardial infarction, limb ischemia, pulmonary edema, hypertension

Gastrointestinal disorders: nausea, vomiting

Metabolic: insulin resistance, hypokalemia, lactic acidosis

Nervous system disorders: headache, paresthesia, tremor, stroke, central nervous system bleeding, weakness, dizziness, disorientation, impaired memory, panic, psychomotor agitation, somnolence

Psychiatric disorders: anxiety

Skin and subcutaneous tissue disorders: diaphoresis, pallor, piloerection, skin blanching, skin necrosis with extravasation.

7 DRUG INTERACTIONS

7.1 Drugs Antagonizing Pressor Effects of Epinephrine

- α-blockers, such as phentolamine
- Vasodilators, such as nitrates
- Diuretics
- Antihypertensives
- Ergot alkaloids

- Phenothiazine antipsychotics

7.2 Drugs Potentiating Pressor Effects of Epinephrine

- Sympathomimetics
- β-blockers, such as propranolol
- Tricyclic anti-depressants
- Monoamine oxidase (MAO) inhibitors
- Catechol-O-methyl transferase (COMT) inhibitors, such as entacapone
- Clonidine
- Doxapram
- Oxytocin

7.3 Drugs Potentiating Arrhythmogenic Effects of Epinephrine

Patients who are concomitantly receiving any of the following drugs should be observed carefully for the development of cardiac arrhythmias *[see Warnings and Precautions (5.5) and Adverse Reactions (6)]*.

- β-blockers, such as propranolol
- Cyclopropane or halogenated hydrocarbon anesthetics, such as halothane
- Antihistamines
- Thyroid hormones
- Diuretics
- Cardiac glycosides, such as digitalis glycosides
- Quinidine

7.4 Drugs Potentiating Hypokalemic Effects of Epinephrine

- Potassium depleting diuretics
- Corticosteroids
- Theophylline

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Prolonged experience with epinephrine use in pregnant women over several decades, based on published literature, do not identify a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with hypotension associated with shock, and treatment with epinephrine should not be delayed *(see Clinical Considerations)*. In animal reproduction studies, epinephrine administered by the subcutaneous route to pregnant rabbits, mice, and hamsters, during the period of organogenesis, resulted in adverse developmental effects (including gastroschisis, and embryonic lethality, and delayed skeletal ossification) at doses approximately 2 times the maximum recommended daily intravenous dose *(see Data)*.

All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the

indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Hypotension associated with septic shock is a medical emergency in pregnancy which can be fatal if left untreated. Delaying treatment in pregnant women with hypotension associated with septic shock may increase the risk of maternal and fetal morbidity and mortality. Do not withhold life-sustaining therapy for a pregnant woman.

Labor or Delivery

Epinephrine usually inhibits spontaneous or oxytocin induced contractions of the pregnant human uterus and may delay the second stage of labor. Avoid epinephrine during the second stage of labor. In dosage sufficient to reduce uterine contractions, the drug may cause a prolonged period of uterine atony with hemorrhage. Avoid epinephrine in obstetrics when maternal blood pressure exceeds 130/80 mmHg.

Although epinephrine improves maternal hypotension associated with anaphylaxis, it may result in uterine vasoconstriction, decreased uterine blood flow, and fetal anoxia.

Data

Animal Data

In an embryofetal development study with pregnant rabbits dosed during the period of organogenesis (on days 3 to 5, 6 to 7 or 7 to 9 of gestation), epinephrine caused teratogenic effects (including gastroschisis) at doses approximately 15 times the maximum recommended intramuscular,subcutaneous, or intravenous dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1.2 mg/kg/day for two to three days). Animals treated on days 6 to 7 had decreased number of implantations.

In an embryofetal development study, pregnant mice were administered epinephrine (0.1 to 10

mg/kg/day) on Gestation Days 6 to 15. Teratogenic effects, embryonic lethality, and delays in skeletal ossification were observed at approximately 3 times the maximum recommended intramuscular, subcutaneous, or intravenous dose (on a mg/m^2 basis at maternal subcutaneous dose of 1 mg/kg/day for 10 days). These effects were not seen in mice at approximately 2 times the maximum recommended daily intramuscular or subcutaneous dose (on a mg/m^2 basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

In an embryofetal development study with pregnant hamsters dosed during the period of organogenesis from gestation days 7 to 10, epinephrine produced reductions in litter size and delayed skeletal ossification at doses approximately 2 times the maximum recommended intramuscular, subcutaneous, or intravenous dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 mg/kg/day).

8.2 Lactation

Risk Summary

There are no data on the presence of epinephrine or its metabolite in human milk, the effects of epinephrine on the breastfed infant, or on human milk production. However, because of its poor oral bioavailability and short half-life, transfer of epinephrine into breastmilk is expected to be low.

Treatment for hypotension associated with septic shock in breastfeeding patients should not be delayed.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of epinephrine for the treatment of hypotension associated with septic shock 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. Avoid veins in the leg in geriatric patients.

10 OVERDOSAGE

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Epinephrine overdosage may also cause transient bradycardia followed by tachycardia and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Myocardial ischemia and infarction, cardiomyopathy, extreme pallor and coldness of the skin, metabolic acidosis due to elevated blood lactic acid levels, and renal insufficiency and failure have also been reported.

Epinephrine is rapidly inactivated in the body and treatment following overdose is primarily supportive. Treatment of pulmonary edema consists of a rapidly acting alpha-adrenergic blocking drug (such as phentolamine mesylate) and respiratory support. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug (such as propranolol). If necessary, pressor effects may be counteracted by rapidly acting vasodilators (such as nitrites) or alpha-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

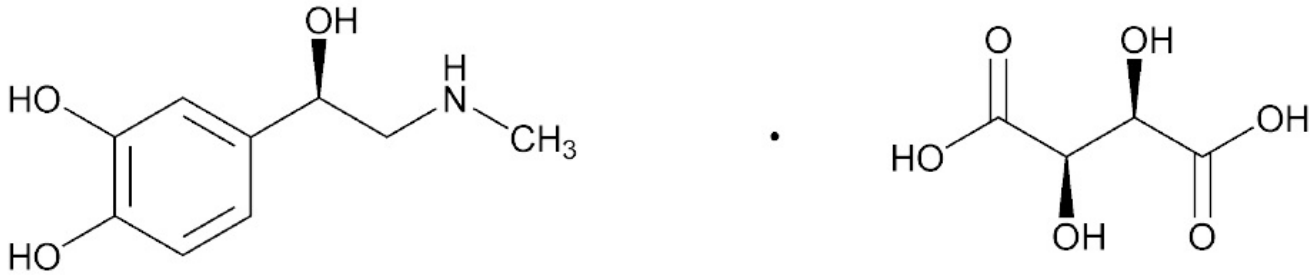
11 DESCRIPTION

Epinephrine in 0.9% Sodium Chloride Injection is a clear, colorless sterile solution containing 16 mg (64 mcg epinephrine base per mL which is equivalent to 116.4 mcg

epinephrine bitartrate) epinephrine, USP in 250 mL VIAFLO bag. In 250 ml VIAFLO bag, each 1 mL of Epinephrine in 0.9% Sodium Chloride Injection solution contains 0.032 mg edetate disodium, 9 mg sodium chloride, 0.05 mg sodium metabisulfite, water for injection. Hydrochloric acid and/or sodium hydroxide to adjust pH range of 3.4 to 4.5.

This sterile solution is to be administered by the intravenous route.

Epinephrine Bitartrate, USP is a sympathomimetic catecholamine (adrenergic agent) designated chemically as 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, *(R)*-,[*R*-(*R**,*R**)]-2,3-dihydroxybutanedioate (1:1) (salt), a white or greyish-white or light brownish-grey, odourless, crystalline powder. Slowly darkens on exposure to air and light. It has the following structural formula:



The molecular weight of epinephrine bitartrate is 333.3 and molecular formula is $C_9H_{13}NO_3 \bullet C_4H_6O_6$.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

VIAFLO container is a flexible plastic container fabricated from a multilayer sheeting composed of Polypropylene (PP), Polyamide (PA) and Polyethylene (PE). The amount of water that can permeate from the container into the overpouch is insufficient to affect the solution significantly. Solutions in contact with the flexible container can leach out certain of the container's chemical components in very small amounts within the expiration period. The suitability of the container material has been confirmed by tests in animals according to USP biological tests for plastic containers.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Epinephrine acts on both alpha (α)- and beta (β)-adrenergic receptors. The mechanism of the rise in blood pressure is 3-fold: a direct myocardial stimulation that increases the strength of ventricular contraction (positive inotropic action), an increased heart rate (positive chronotropic action), and peripheral vasoconstriction.

12.2 Pharmacodynamics

When administered parenterally epinephrine has a rapid onset and short duration of action.

Following intravenous administration of epinephrine, increases in systolic blood pressure and heart rate are observed. Decreases in systemic vascular resistance and diastolic blood pressure are observed at low doses of epinephrine because of β_2-mediated vasodilation, but are overtaken by α_1-mediated peripheral vasoconstriction at higher doses leading to increase in diastolic blood pressure. The onset of blood pressure increase following an intravenous dose of epinephrine is < 5 minutes and the time to offset blood pressure response occurs within 20 min. Most vascular beds are constricted including renal, splanchnic, mucosal and skin.

Epinephrine increases glycogenolysis, reduces glucose up take by tissues, and inhibits insulin release in the pancreas, resulting in hyperglycemia and increased blood lactic acid.

12.3 Pharmacokinetics

Following intravenous injection, epinephrine is rapidly cleared from the plasma with an effective half-life of < 5 min. A pharmacokinetic steady state following continuous intravenous infusion is achieved within 10 to 15 min. In patients with septic shock, epinephrine displays dose-proportional pharmacokinetics in the infusion dose range of 0.03 to 1.7 mcg/kg/min.

Epinephrine is extensively metabolized with only a small amount excreted unchanged. Epinephrine is rapidly degraded to vanillylmandelic acid, an inactive metabolite, by monoamine oxidase and catechol-O-methyltransferase that are abundantly expressed in the liver, kidneys and other extraneuronal tissues. The tissues with the highest contribution to removal of circulating exogenous epinephrine are the liver (32%), kidneys (25%), skeletal muscle (20%), and mesenteric organs (12%).

Specific Populations

Age

In a pharmacokinetic study of 45-minute epinephrine infusions given to healthy men aged 20 to 25 years and healthy men aged 60 to 65 years, the mean plasma metabolic clearance rate of epinephrine at steady state was greater among the older men (144.8 versus 78 mL/kg/min for a 14.3 ng/kg/min infusion).

Body Weight

Body weight has been found to influence epinephrine pharmacokinetics. Higher body weight was associated with a higher plasma epinephrine clearance and a lower concentration plateau.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of epinephrine have not been conducted.

Epinephrine and other catecholamines have been shown to have mutagenic potential *in vitro*. Epinephrine was positive in the *Salmonella* bacterial reverse mutation assay, positive in the mouse lymphoma assay, and negative in the *in vivo* micronucleus assay. Epinephrine is a mutagen based on the *E. coli* WP2 Mutoxitest bacterial reverse mutation

assay.

The potential for epinephrine to impair reproductive performance has not been evaluated, but epinephrine has been shown to decrease implantation in female rabbits dosed subcutaneously with 1.2 mg/kg/day (15-fold the highest human intramuscular or subcutaneous daily dose) during gestation days 3 to 9.

13.2 Animal Toxicology and/or Pharmacology

Epinephrine was associated with metabolic effects, decreased mesentery, coronary and renal conductance in a sheep model of septic shock. Data from hemolysis study have shown that epinephrine at 1:1000 dilution is non-hemolytic. Epinephrine infusion significantly increased the MAP (69 vs. 86 mmHg) and cardiac output (6.4 vs. 7.1 L/min) and decreased renal blood flow (330 vs. 247 mL/min).

14 CLINICAL STUDIES

14.1 Hypotension associated with Septic Shock

Fourteen clinical studies from the literature documented that epinephrine increases the mean arterial pressure (MAP) in patients with hypotension associated with septic shock.

16 HOW SUPPLIED/STORAGE AND HANDLING

Epinephrine in 0.9% Sodium Chloride Injection is a clear and colorless solution filled in a single dose 250 mL VIAFLO container. Epinephrine in 0.9% Sodium Chloride Injection is supplied as a carton of 20 bags in a 16 mg/250 mL (64 mcg/mL) strength, NDC 0338-0024-20.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Epinephrine is light sensitive. Protect from light until ready to use. Store in overpouch until time of use.

Protect from alkalis and oxidizing agents.

VIAFLO container is not made with natural rubber latex, DEHP, or PVC.

Manufactured for:
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Ireland

CB-30-03-117

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – Epinephrine in 0.9% Sodium Chloride Injection, 16 mg/250 mL

NDC 0338-**0024**-20

Rx only

Epinephrine in 0.9% Sodium Chloride Injection

16 mg/250 mL
(64 mcg/mL)

250 mL

Warning: check concentration and infusion rate

For Intravenous Infusion Only
Ready to Use.
Single-Dose Only - Discard unused portion.
Not for Ophthalmic Use.

Each mL contains Epinephrine Bitartrate 116.4 mcg which is equivalent to Epinephrine base 64 mcg, Edetate Disodium 0.032 mg, Sodium Chloride 9 mg, Sodium Metabisulfite 0.05 mg, Water for Injection. Hydrochloric Acid and/or Sodium Hydroxide to adjust pH range of 3.4 to 4.5.

Dosage: See Prescribing Information.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Epinephrine is light sensitive. Protect from light until ready to use.
Store in overpouch until time of use.

After removing the overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

VIAFLO container is not made with natural rubber latex, DEHP, or PVC.

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Baxter

Manufactured for:
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Ireland

(01)00303380024209

EZPE8835
CB-35-05-612

DO NOT USE THIS PORT

LOT

EXP

NDC 0338-**0024**-20

Rx Only

Epinephrine
in 0.9% Sodium Chloride Injection

16 mg/250 mL
(64 mcg/mL)

250 mL

Warning: check concentration and infusion rate

For Intravenous Infusion Only

Ready to Use.

Single-Dose Only - Discard unused portion.

Not for Ophthalmic Use.

Each mL contains Epinephrine Bitartrate **116.4 mcg** which is equivalent to Epinephrine base **64 mcg**, Edetate Disodium **0.032 mg**, Sodium Chloride **9 mg**, Sodium Metabisulfite **0.05 mg**, Water for Injection. Hydrochloric Acid and/or Sodium Hydroxide to adjust pH range of 3.4 to 4.5.

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Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Epinephrine is light sensitive. Protect from light until ready to use. Store in overpouch until time of use.

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After removing the overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

VIAFLO container is not made with natural rubber latex, DEHP, or PVC.

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Manufactured for:
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Ireland

EZPE8835
CB-35-05-612

DO NOT USE
THIS PORT

LOT

EXP

TO OPEN: TEAR AT NOTCH

NDC 0338-**0024**-20

Rx only

Epinephrine in 0.9% Sodium Chloride Injection

16 mg/250 mL
(64 mcg/mL)

250 mL

Warning: check concentration and infusion rate

For Intravenous Infusion Only

Ready to Use.
Single-Dose Only - Discard unused portion.
Not for Ophthalmic Use.

Each mL contains Epinephrine Bitartrate **116.4 mcg** which is equivalent to Epinephrine base **64 mcg,** Edetate Disodium **0.032 mg**, Sodium Chloride **9 mg**, Sodium Metabisulfite **0.05 mg**, Water for Injection. Hydrochloric Acid and/or Sodium Hydroxide to adjust pH range of 3.4 to 4.5.

Dosage: See Prescribing Information.

TO OPEN: TEAR AT NOTCH. Do not use if overpouch has been previously opened or damaged. Use unit promptly once overpouch is removed.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Epinephrine is light sensitive. Protect from light until ready to use.
Store in overpouch until time of use.

The container closure is not made with natural rubber latex.

(91)CB1001260

EZPE8835
CB-10-01-260

Baxter
Manufactured for:
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Ireland

(01)00303380024209

(See Solution Container for Lot and Exp)

TO OPEN: TEAR AT NOTCH

NDC 0338-**0024**-20

Rx Only

Epinephrine
in 0.9% Sodium Chloride Injection

16 mg/250 mL
(64 mcg/mL)

250 mL

Warning: check concentration and infusion rate

For Intravenous Infusion Only

Ready to Use.

Single-Dose Only - Discard unused portion.

Not for Ophthalmic Use.

Each mL contains Epinephrine Bitartrate **116.4 mcg** which is equivalent to Epinephrine base **64 mcg**, Edetate Disodium **0.032 mg**, Sodium Chloride **9 mg**, Sodium Metabisulfite **0.05 mg**, Water for Injection. Hydrochloric Acid and/or Sodium Hydroxide to adjust pH range of 3.4 to 4.5.

Dosage: See Prescribing Information.

TO OPEN: TEAR AT NOTCH. Do not use if overpouch has been previously opened or damaged. Use unit promptly once overpouch is removed.

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The container closure is not made with natural rubber latex.

Baxter
Manufactured for:
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Ireland

EZPE8835
CB-10-01-260

(See Solution Container for Lot and Exp)

EPINEPHRINE
epinephrine injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0024
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE BITARTRATE (UNII: 30Q7KI53AK) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	64 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.032 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	0.05 mg in 1 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0024-20	20 in 1 CARTON	02/28/2025	
1		250 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA218475	02/28/2025	

Labeler - Baxter Healthcare Corporation (005083209)

Registrant - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Vantive Manufacturing LImited		986154341	ANALYSIS(0338-0024) , LABEL(0338-0024) , MANUFACTURE(0338-0024) , PACK(0338-0024) , STERILIZE(0338-0024)

Revised: 7/2025 Baxter Healthcare Corporation