



EPINEPHRINE Injection, USP

| PRODUCT DESCRIPTION | DELIVERY SYSTEM | UNIT SIZE | UNITS / BOX | NDC# |
|----------------------------|-----------------|-----------------------|-------------|--------------|
| Epinephrine Injection, USP | Multi-Dose Vial | 30 mg/30 mL (1 mg/mL) | 1 | 76329-9060-0 |

| WHOLESALE ITEM NUMBERS | | | |
|------------------------|----------|----------|------------------|
| AMERISOURCEBERGEN | CARDINAL | MCKESSON | MORRIS & DICKSON |
| 10235600 | 5644877 | 3948742 | 903195 |

TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136

INTERNATIONAL MEDICATION SYSTEMS, LTD
1886 Santa Anita Ave., South El Monte, CA 91733
www.ims-limited.com
An Amphastar Pharmaceuticals Company



Rx Only
05/20
01-021-06

EPINEPHRINE Injection, USP

30 mg/30 mL (1 mg/mL)

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

The full prescribing information for Epinephrine Injection, USP is available at www.Amphastar.com.

EPINEPHRINE injection 1 mg/mL, for intramuscular, subcutaneous, and intravenous use

Initial U.S. Approval: 1939

RECENT MAJOR CHANGES

| | |
|--|---------|
| Indications and Usage (1.2) | 01/2019 |
| Dosage and Administration (2.3) | 01/2019 |
| Warnings and Precautions (5.3, 5.4, 5.5, 5.6, 5.7) | 01/2019 |

INDICATIONS AND USAGE

Epinephrine Injection, USP is a non-selective alpha and beta adrenergic agonist indicated for:

- Emergency treatment of allergic reactions (Type 1), including anaphylaxis (1.1)
- To increase mean arterial blood pressure in adult patients with hypotension associated with septic shock (1.2)

DOSAGE AND ADMINISTRATION

- Anaphylaxis:
 - *Adults and Children 30 kg (66 lbs) or more:* 0.3 to 0.5 mg (0.3 mL to 0.5 mL) intramuscularly or subcutaneously into anterolateral aspect of the thigh every 5 to 10 minutes as necessary (2.2)
 - *Children 30 kg (66 lbs) or less:* 0.01 mg/kg (0.01 mL/kg), up to 0.3 mg (0.3 mL), intramuscularly or subcutaneously into anterolateral aspect of the thigh every 5 to 10 minutes as necessary (2.2)
- Hypotension associated with septic shock:
 - Dilute epinephrine in dextrose solution prior to infusion (2.3)
 - Infuse epinephrine into a large vein (2.3)
 - Intravenous infusion rate of 0.05 mcg/kg/min to 2 mcg/kg/min, titrated to achieve desired mean arterial pressure (2.3)
 - Wean gradually (2.3)
 - See Full Prescribing Information for instructions on dilution and administration of the injection.

DOSAGE FORMS AND STRENGTHS

Injection: 30 mg/ 30 mL (1 mg/mL) multiple dose vial (3)

ADVERSE REACTIONS

Common adverse reactions to systemically administered epinephrine include anxiety, tremor, weakness, dizziness, sweating, palpitations and pallor (6)

To report SUSPECTED ADVERSE REACTIONS, contact Amphastar Pharmaceuticals, Inc. at 1-800-423-4136 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Drugs that counter the pressor effects of epinephrine include alpha blockers, vasodilators such as nitrates, diuretics, antihypertensives and ergot alkaloids. (7.1)
- Drugs that potentiate the effects of epinephrine include sympathomimetics, beta blockers, tricyclic antidepressants, MAO inhibitors, COMT inhibitors, clonidine, doxapram, oxytocin, levothyroxine sodium, quinidine and certain antihistamines. (7.2)
- Drugs that increase the arrhythmogenic potential of epinephrine include beta blockers, cyclopropane and halogenated hydrocarbon anesthetics, 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. (7.4)

USE IN SPECIFIC POPULATIONS

- Elderly patients and pregnant women may be at greater risk of developing adverse reactions when epinephrine is administered parenterally (8.1, 8.5)
- Pregnancy: May cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2019