

EPINEPHRINE PROFESSIONAL EMS- epinephrine convenience kit

Focus Health Group

Epinephrine Professional EMS Convenience Kit



Dosage and Administration:

Always follow the prescriber's order for dosing and administration.

Adrenamine may be administered for anaphylaxis:

- o Adults and Children 30 kg (66 lbs) or more: 0.3 to 0.5 mg (0.3 to 0.5 mL) intramuscularly or subcutaneously into anterolateral aspect of the thigh every 5 to 10 minutes as necessary
- o 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

PDP

CALL 911

In conjunction with administering epinephrine, call 911 immediately and advise dispatchers of a suspected anaphylactic reaction and arrange for the patient to be transported to an emergency room for observation and/or additional treatment.



NDC 24357-012-12 RX ONLY
CONVENIENCE KIT INCLUDES
 (1) Epinephrine Injection 1 mg/mL Vial
 (2) 1 mL Syringe with 25G Safety Needle
 (4) Alcohol Prep Pads
 (1) Package Insert and (1) Instructions
 You are encouraged to report any negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
 Manufactured by: Focus Health Group • 5802 Kingston Pike • Knoxville, TN 37919

Follow your prescriber's product or order for dosage and administration. For treating anaphylaxis: Adults and Children 30 kg (66 lb) or more: 0.3 to 0.5 mg (0.3 to 0.5 mL) intramuscularly or subcutaneously into anterolateral aspect of the thigh every 5 to 10 minutes as necessary. Children 20 kg (44 lb) or less: 0.1 mg/kg (0.1 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. Do not inject into the buttocks, digits, hands, or feet. Do not administer repeated injections at the same site, as the resulting vasoconstriction may cause tissue necrosis. Inspect vial(s) for particulate matter and discoloration prior to administration. Do not use if the solution is colored or cloudy, or if it contains particulate matter. Product epinephrine from light and freezing. Store at 20 to 25 °C (68 to 77 °F). May aggravate angina pectoris or produce ventricular arrhythmias, particularly in patients with underlying heart disease. Adverse reactions with caution were used intramuscularly or subcutaneously. Patients with Tricyclic Antidepressant, Phenytoin & disulfiram or Phenytoin/Carbamazepine are at greater risk for having adverse reactions when used intramuscularly or subcutaneously. See package insert for Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, and Overdose.

EPINEPHRINE PROFESSIONAL EMS

EPINEPHRINE CONVENIENCE KIT with SAFETY SEAL

NDC 24357-012-12 RX ONLY
EPINEPHRINE PROFESSIONAL
 EPINEPHRINE CONVENIENCE KIT with SAFETY SEAL



EPINEPHRINE 1mg/mL
 See back for proper dosage and administration

- For intramuscular or subcutaneous use
- Keep out of reach of children
- Not for ophthalmic use
- Light sensitive, protect from light and freezing
- Store at 20 to 25 °C (68 to 77 °F)
- Single use only

EPINEPHRINE PROFESSIONAL EMS

EPINEPHRINE CONVENIENCE KIT with SAFETY SEAL

EPINEPHRINE PROFESSIONAL EMS

epinephrine convenience kit kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:24357-012
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:24357-012-12	1 in 1 CARTON; Type 0: Not a Combination Product	07/01/2019
Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 VIAL	1 mL	
Part 2	4 PACKET	4 mL	
Part 1 of 2			
ADRENALIN			
epinephrine injection			

Product Information

Item Code (Source)	NDC:42023-159
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	0.457 mg in 1 mL
TARTARIC ACID (UNII: W4888I119H)	2.25 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	1 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	7.3 mg in 1 mL
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42023-159-01	1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA204200	07/01/2013	

Part 2 of 2

MCKESSON ALCOHOL PREP PAD

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:68599-5804
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-5804-1	1 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/09/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA204200	07/01/2019	

Labeler - Focus Health Group (826939949)**Registrant** - Focus Health Group (826939949)**Establishment**

Name	Address	ID/FEI	Business Operations
Par Sterile Products LLC		808402890	manufacture(42023-159)

Establishment

Name	Address	ID/FEI	Business Operations
Focus Health Group		826939949	label(24357-012)