NOREPINEPHRINE BITARTRATE - norepinephrine bitartrate injection, solution
Cantrell Drug Company

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Norepinephrine Bitartrate 16 mg Added to 5% Dextrose 250 mL Bag

• WARNINGS AND PRECAUTIONS

Outsourced Compounded Drug. Not for Resale. Hospital/Office Use Only.

• ADVERSE EVENTS

To facilitate Adverse Event Reporting: www.fda.gov/medwatch or 1-800-FDA-1088.

• HOW SUPPLIED

Norepinephrine bitartrate injection solution is supplied as a sterile, nonpyrogenic solution that is clear, colorless at 250 mL in a Single-Dose Injection Solution Bag.

This product is Preservative-Free and Latex-Free.

• INGREDIENTS

Each 1 mL contains the equivalent of 64 mcg norepinephrine base, 50 mg dextrose, 473.6 mcg sodium chloride, 128 mcg sodium metabisulfite, and pH adjusters include hydrochloric acid and/or sodium hydroxide, if necessary.

• STORAGE AND HANDLING

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

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

Do not use the solution if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

• DOSAGE AND ADMINISTRATION.

FOR INTRAVENOUS USE ONLY. PRESERVATIVE-FREE INJECTION SOLUTION.

Rx Only

Rev. 03/15

CANTRELL DRUG COMPANY
LITTLE ROCK, AR 72207

NOREPINEPHRINE BITARTRATE

norepinephrine bitartrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52533-164
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Norepinephrine Bitartrate (UNII: IFY5PE3ZRW) (Norepinephrine - UNII:X4W3ENH1CV)	Norepinephrine	64 ug in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	50 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	473.6 ug in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	128 ug in 1 mL
WATER (UNII: 059QF0KO0R)	

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
May contain	**HYDROCHLORIC ACID** (UNII: QTT17582CB)	
May contain	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52533-164-18	250 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/12/2015	

Labeler - Cantrell Drug Company (035545763)

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