

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 8 mg Added to 5% Dextrose 250 mL Bag

Norepinephrine 8 mg **Bitartrate**

Added to

5% Dextrose 250 mL Bag

(32 mcg/mL*)

LOT: xxxxx

BUD:

Compounded Date: 03/13



Volume: 250 mL* Total Dose: 8mg/250mL*

**Volume and Concentration Excludes Additive and Manufacturer Overfill.*

Each mL Contains: Norepinephrine Bitartrate (eq to 32 mcg Norepinephrine Base),
Dextrose 50 mg, Sodium Chloride 236.8 mcg, Sodium Metabisulfite 64 mcg.
pH adj: Hydrochloric Acid/Sodium Hydroxide.

Store at Room Temperature. Protect from Light.
Single-Dose Bag. Injection Solution for IV Use.

NDC: 52533-166-18



(01) 0 0352533 16618 1

Rx Only

Hospital/Office Use Only.

Outsourced Compounded Drug. Not for Resale.



CANTRELL DRUG COMPANY
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• WARNINGS AND PRECAUTIONS

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• **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 32 mcg norepinephrine base, 50 mg dextrose, 236.8 mcg sodium chloride, 64 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:52533-166
Route of Administration	INTRAVENOUS		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Norepinephrine Bitartrate (UNII: IFY5PE3ZRW) (Norepinephrine - UNII:X4W3ENH1CV)	Norepinephrine	32 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DEXTROSE (UNII: 5SLOG7R0OK)	50 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	236.8 ug in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	64 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:52533-166-18	250 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/06/2015	

Labeler - Cantrell Drug Company (035545763)

Revised: 3/2015

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