

**ACETYLCYSTEINE- acetylcysteine injection, solution**  
**Cadila Healthcare Limited**

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**ACETYLCYSTEINE INJECTION**

**PRINCIPAL DISPLAY PANEL – Vial Label**

NDC 70771-1412-1

**Acetylcysteine Injection**

**6 g/30 mL**

(200 mg/mL)

**MUST BE FURTHER DILUTED  
PRIOR TO INTRAVENOUS USE**

30 mL Sterile

Rx only

(01)00370771141210

Code No.: GUJ/DRUG/1081

Manufactured by:  
Cadila Healthcare Limited  
Ahmedabad, India

**NDC 70771-1412-1**

**Acetylcysteine  
Injection**

**6 g/30 mL**  
(200 mg/mL)

**MUST BE FURTHER DILUTED  
PRIOR TO INTRAVENOUS USE**

**zydus**  
pharmaceuticals

**30 mL Sterile  
Rx only**

Store at controlled room temperature,  
20°C to 25°C (68°F to 77°F).  
Single dose vial, preservative free, discard unused portion.  
Do not use if previously opened.  
DOSAGE: See package insert for dosage information.  
Inactive ingredients: Edetate Disodium,  
Sodium Hydroxide and Water for Injection.  
Vial stoppers do not contain natural rubber latex.

Rev: 07/18  
XXXXXXX

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

**PRINCIPAL DISPLAY PANEL – Carton Label**

NDC 70771-1412-8

**Acetylcysteine Injection**

**6 g/30 mL**

(200 mg/mL)

**MUST BE FURTHER DILUTED  
PRIOR TO INTRAVENOUS USE**

4 X 30 mL Sterile Vials

Rx only



<b>ACETYLCYSTEINE</b>			
acetylcysteine injection, solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1412
<b>Route of Administration</b>	INTRAVENOUS		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
ACETYLCYSTEINE (UNII: WYQ7N0BPYC) (ACETYLCYSTEINE - UNII:WYQ7N0BPYC)		ACETYLCYSTEINE	200 mg in 1 mL
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
EDETATE DISODIUM (UNII: 7FLD91C86K)			
NITROGEN (UNII: N762921K75)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			

WATER (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1412-8	4 in 1 CARTON	01/17/2019	
1	NDC:70771-1412-1	30 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
ANDA	ANDA208166	01/17/2019	

**Labeler** - Cadila Healthcare Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1412) , MANUFACTURE(70771-1412)

Revised: 10/2020

Cadila Healthcare Limited