

ETHACRYNATE SODIUM - ethacrynate sodium injection, powder, lyophilized, for solution

Zydus Lifesciences Limited

Ethacrynate Sodium for Injection, USP

INTRAVENOUS

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 50 MG SINGLE DOSE VIAL CONTAINER LABEL

NDC 70771-1106-1

Ethacrynate Sodium for Injection, USP

50 mg/vial*

*50 mg Ethacrynic Acid Equivalent

For Intravenous Use

SINGLE DOSE VIAL

Rx only

(01) 00170771110618

Discard unused solution after 24 hours.

Vial stoppers do not contain natural rubber latex.

Code No.: GUJ/DRUG/1081

Manufactured by:
Cadila Healthcare Limited
Ahmedabad, India

NDC 70771-1106-1

Ethacrynate Sodium for Injection, USP

50 mg/vial*

*50 mg Ethacrynic Acid Equivalent
For Intravenous Use

zydus pharmaceuticals

SINGLE DOSE VIAL
Rx only

USUAL DOSAGE: See accompanying circular.
Store in a tightly closed container at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature]
Filled into container as a true solution, then cryodesiccated.
To reconstitute, add 50 mL of 5% Dextrose Injection or Sodium Chloride Injection for slow intravenous injection.

Lot: _____
Exp: _____

Rev: 11/17
XXXXXX

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 50 MG SINGLE DOSE VIAL CARTON LABEL

NDC 70771-1106-1

Ethacrynate Sodium for Injection, USP

50 mg/vial*

*50 mg Ethacrynic Acid Equivalent

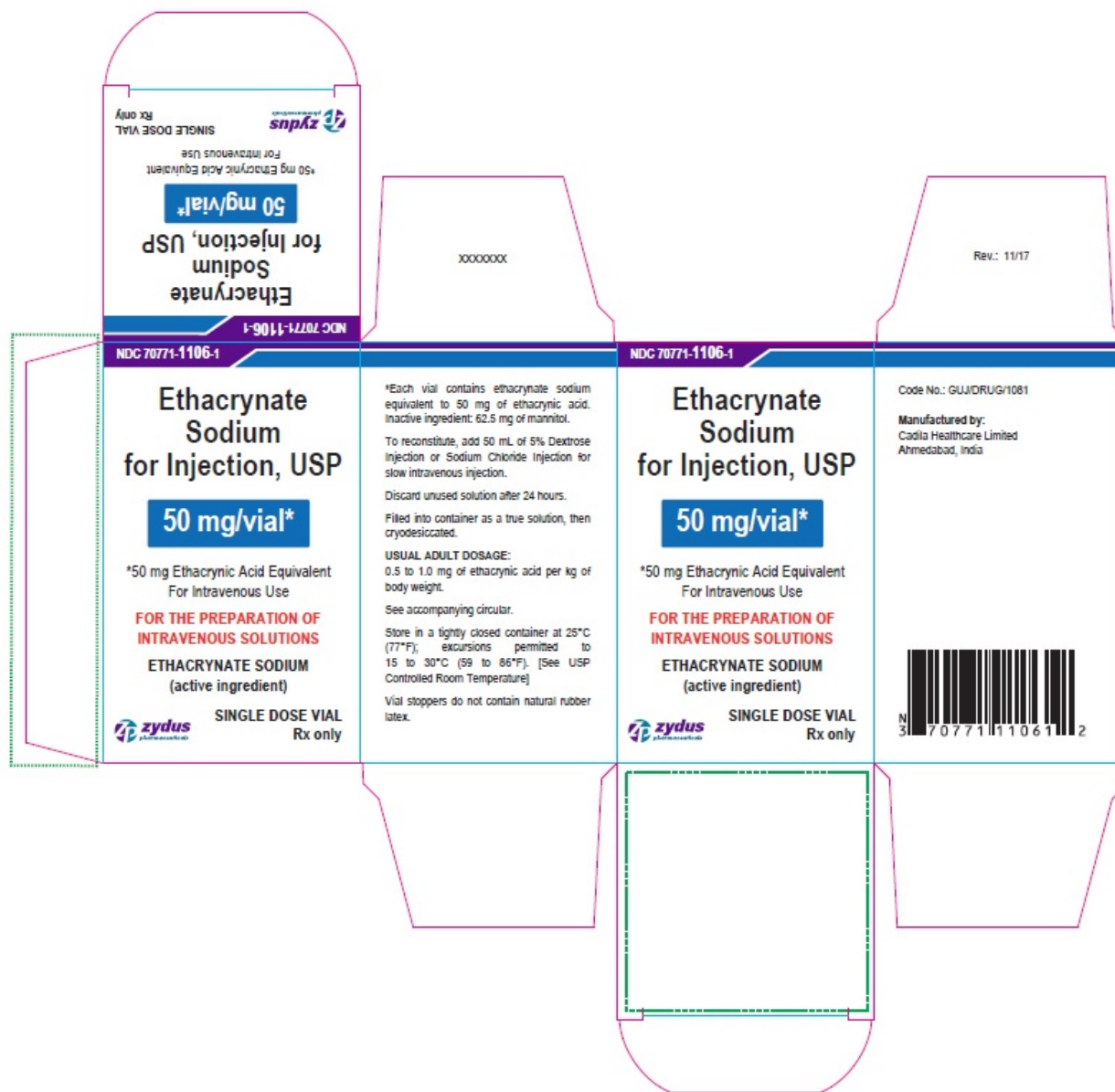
For Intravenous Use

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

ETHACRYNATE SODIUM (active ingredient)

SINGLE DOSE VIAL

Rx only



ETHACRYNATE SODIUM

ethacrynate sodium injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1106	
Route of Administration	INTRAVENOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ETHACRYNATE SODIUM (UNII: K41MYV7MPM) (ETHACRYNIC ACID - UNII:M5DP350VZV)		ETHACRYNIC ACID	50 mg in 50 mL	
Inactive Ingredients				
Ingredient Name		Strength		
MANNITOL (UNII: 3OWL53L36A)		62.5 mg in 50 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1106-1	1 in 1 CARTON	01/24/2018	
1		50 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	ANDA207758	01/24/2018		

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Revised: 10/2022

Zydus Lifesciences Limited