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

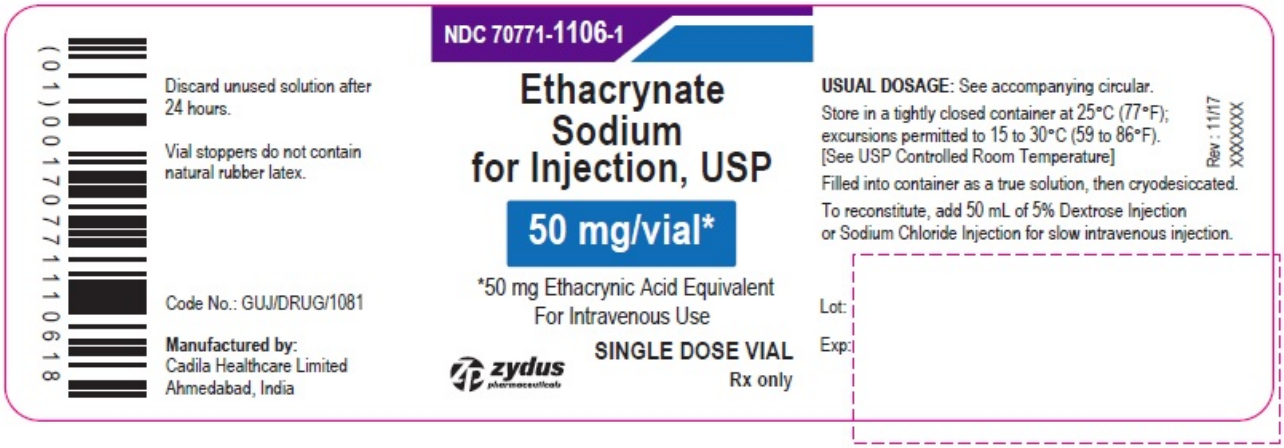
50 mg/vial*

*50 mg Ethacrynic Acid Equivalent

For Intravenous Use

SINGLE DOSE VIAL

Rx only



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