FUROSEMIDE- furosemide injection
Maiva Pharma Private Limited

Rx only

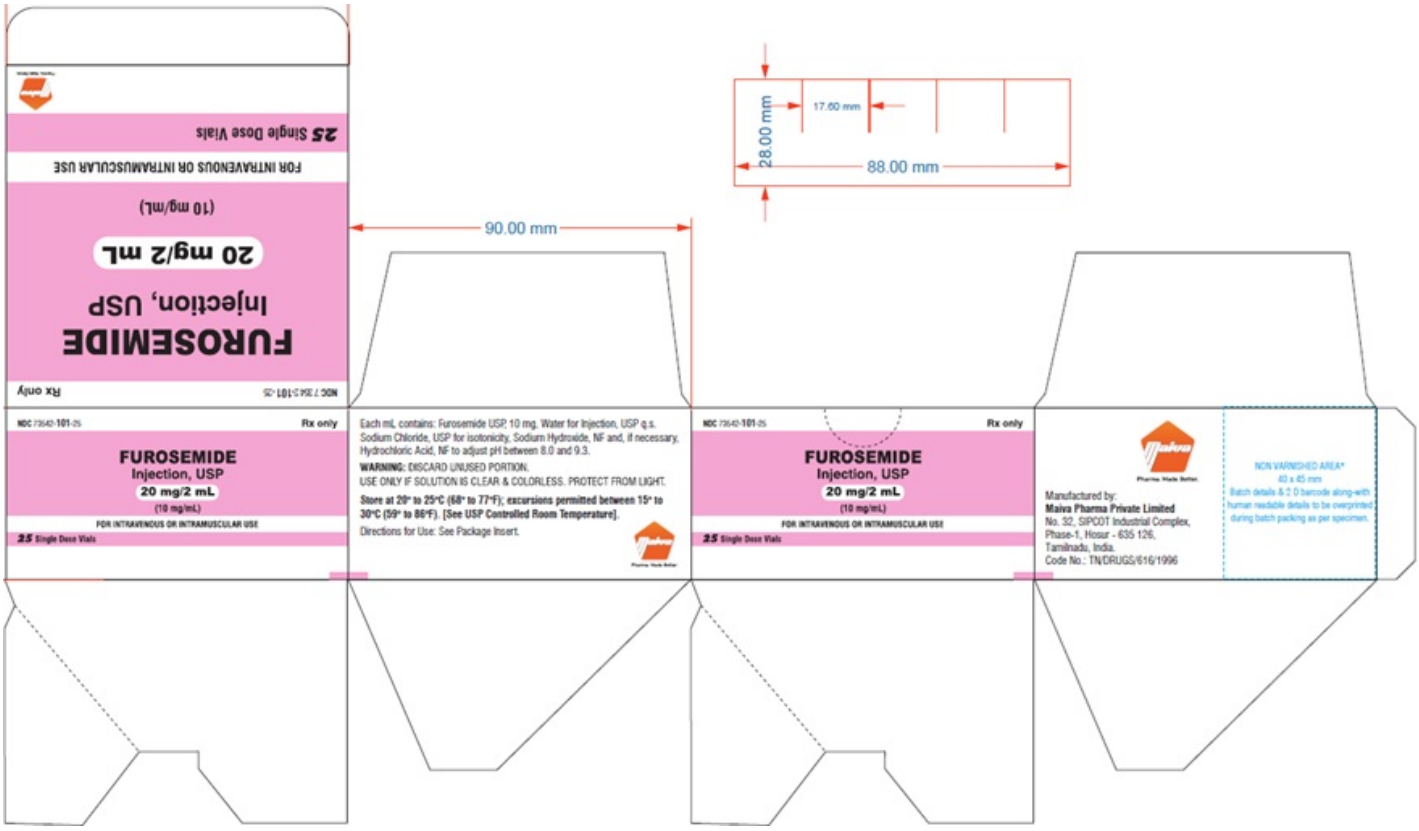
WARNINGS

Furosemide is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required and dose and dose schedule must be adjusted to the individual patient's needs. (See DOSAGE AND ADMINISTRATION.)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

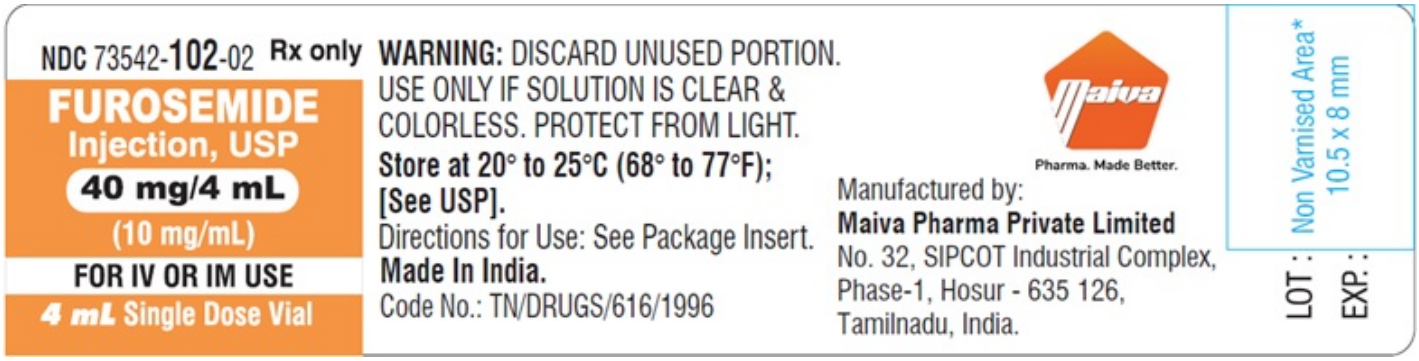
NDC 73542-**101-**01
Furosemide Injection, USP
20 mg/2 mL
(10 mglmL)
FOR IV OR IM USE
Rx only
2 mL Single-Dose vial

NDC 73542-**101**-25
Furosemide Injection, USP
20 mg/2 mL
(10 mglmL)
FOR IV OR IM USE
Rx only
25 Single-Dose vial

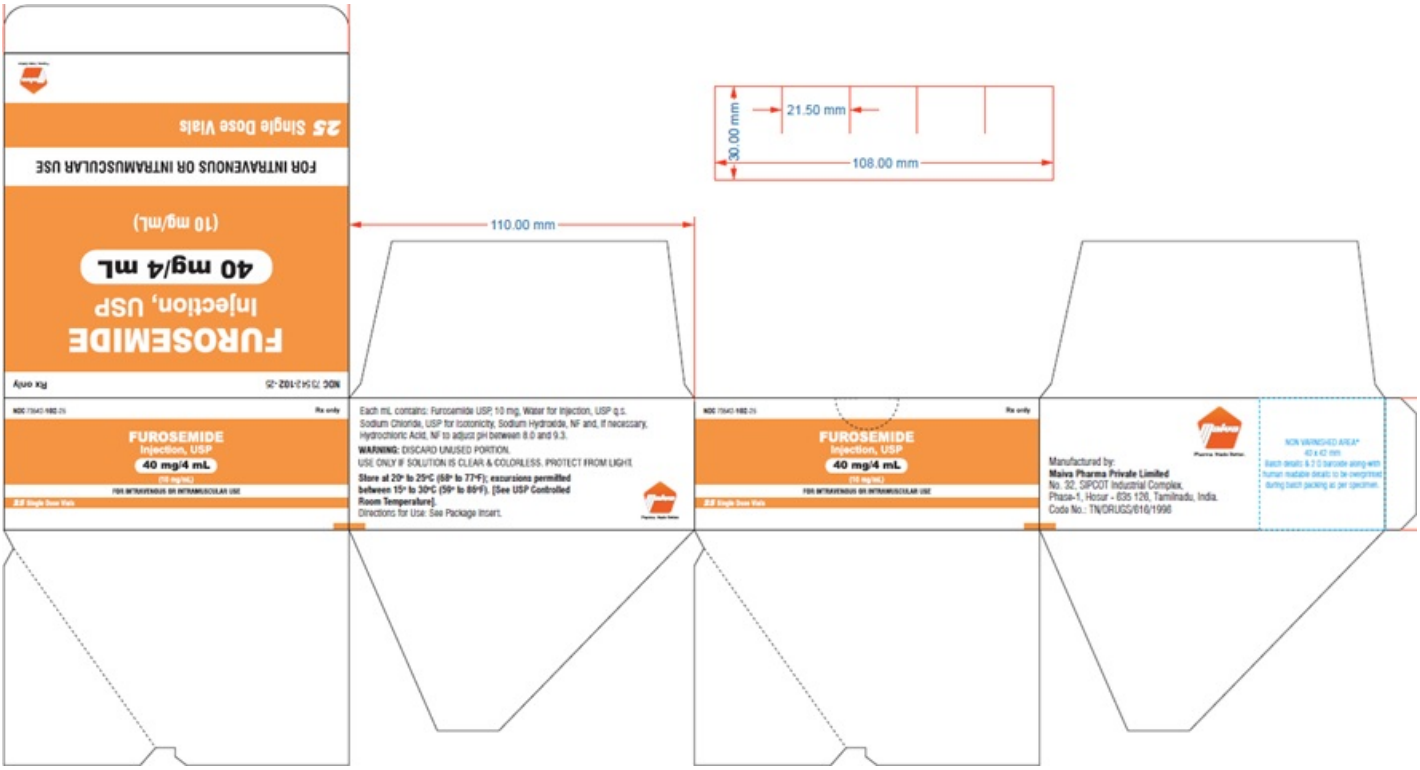


PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 73542-**102**-02
Furosemide Injection, USP
40 mg/4 mL
(10 mglmL)
FOR IV OR IM USE
Rx only
4 mL Single-Dose vial



NDC 73542-**102**-25
Furosemide Injection, USP
40 mg/4 mL
(10 mglmL)
FOR IV OR IM USE
Rx only
25 Single-Dose via



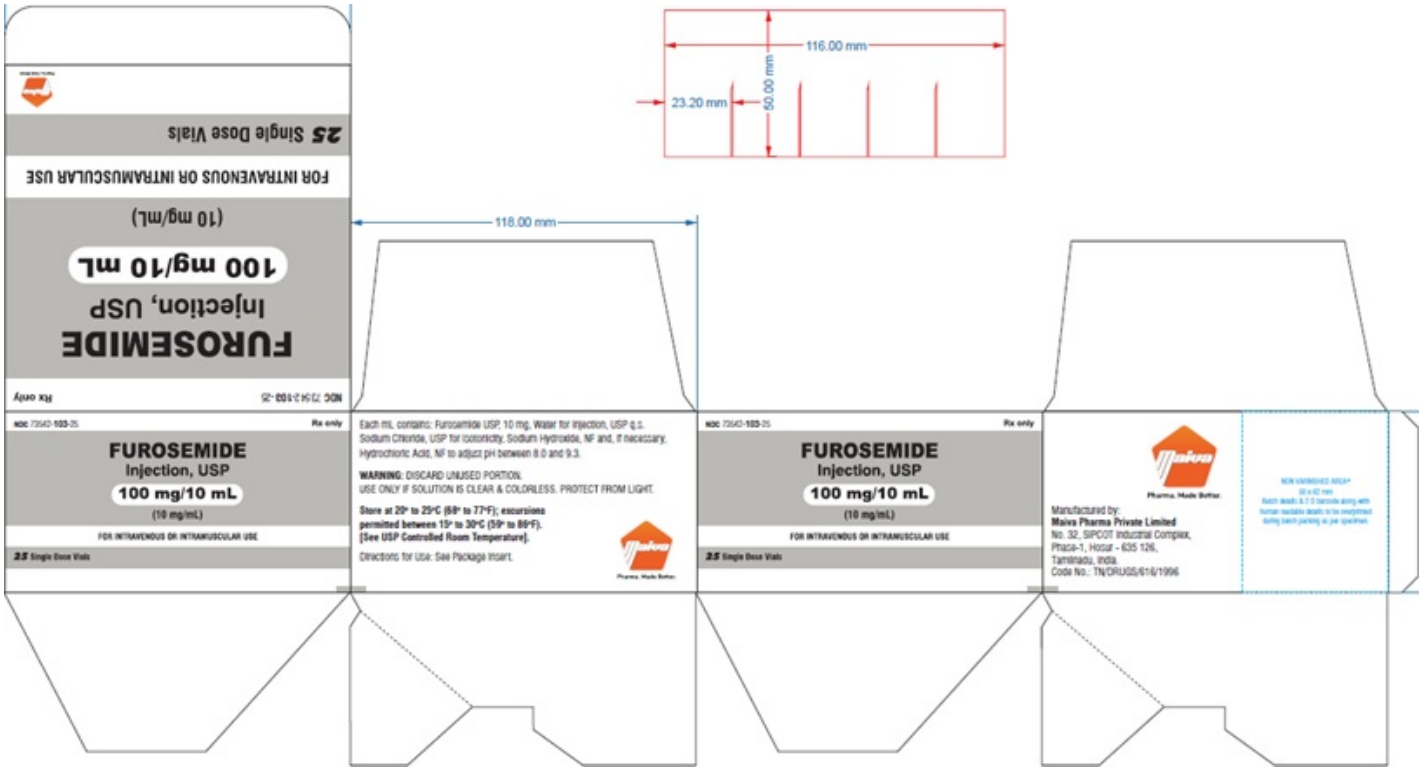
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 73542-**103**-03
Furosemide Injection, USP
100 mg/10 mL
(10 mglmL)
FOR IV OR IM USE
Rx only
10 mL Single-Dose vial

NDC 73542-**103**-25
Furosemide Injection, USP

100 mg/10 mL
(10 mglmL)
FOR IV OR IM USE
Rx only

25 Single-Dose vial



FUROSEMIDE

furosemide injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73542-101
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FUROSEMIDE (UNII: 7LXU5N7ZO5) (FUROSEMIDE - UNII:7LXU5N7ZO5)	FUROSEMIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73542-101-25	25 in 1 CARTON	06/16/2025	
1		2 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	ANDA203428	06/16/2025	

FUROSEMIDE

furosemide injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73542-102
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FUROSEMIDE (UNII: 7LXU5N7ZO5) (FUROSEMIDE - UNII:7LXU5N7ZO5)	FUROSEMIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73542-102-25	25 in 1 CARTON	06/16/2025	
1		4 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	ANDA203428	06/16/2025	

FUROSEMIDE

furosemide injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73542-103
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FUROSEMIDE (UNII: 7LXU5N7ZO5) (FUROSEMIDE - UNII:7LXU5N7ZO5)	FUROSEMIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73542-103-25	25 in 1 CARTON	06/16/2025	
1		10 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	ANDA203428	06/16/2025	

Labeler - Maiva Pharma Private Limited (725656438)

Registrant - Maiva Pharma Private Limited (725656438)

Establishment

Name	Address	ID/FEI	Business Operations
Maiva Pharma			analysis(73542-101, 73542-102, 73542-103) , manufacture(73542-101, 73542-

Private Limited		725656438	102, 73542-103) , pack(73542-101, 73542-102, 73542-103) , label(73542-101, 73542-102, 73542-103)