PEMETREXED - pemetrexed disodium injection, powder, lyophilized, for solution
Zydus Lifesciences Limited

Pemetrexed for injection, for Intravenous Use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1691-1

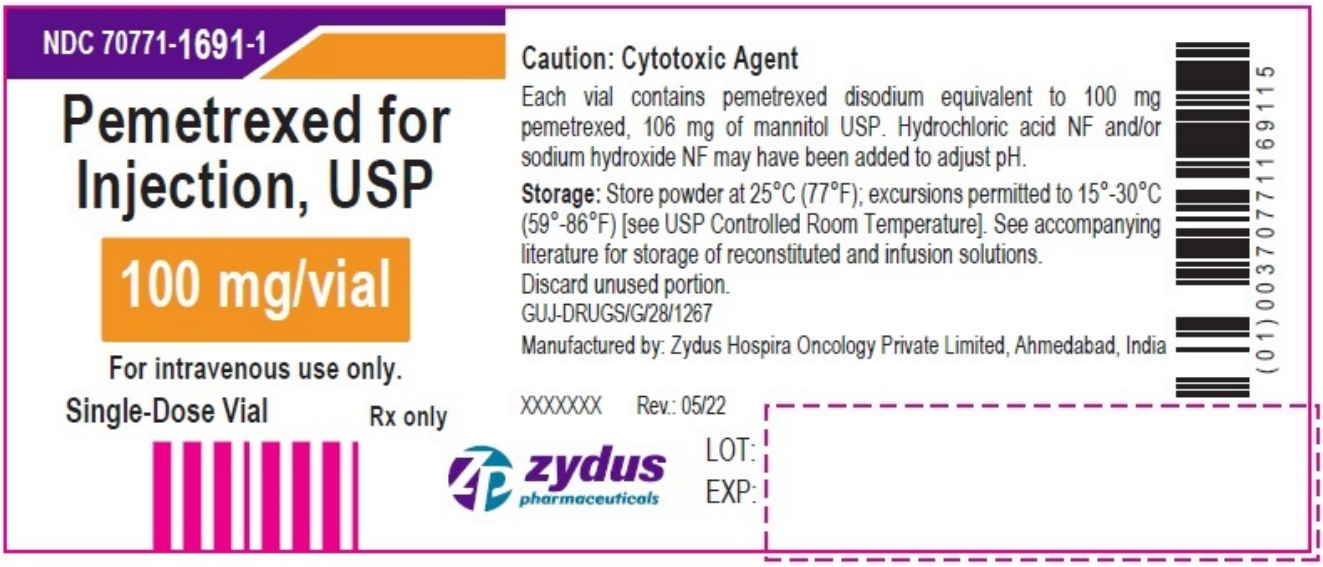
Pemetrexed for Injection, USP

100 mg/vial

For intravenous use only.

Single-Dose Vial

Rx only



NDC 70771-1691-1

Pemetrexed for Injection, USP

100 mg/vial

For intravenous use only.

One Single-Dose Vial Carton

Rx only

NDC 70771-1692-1

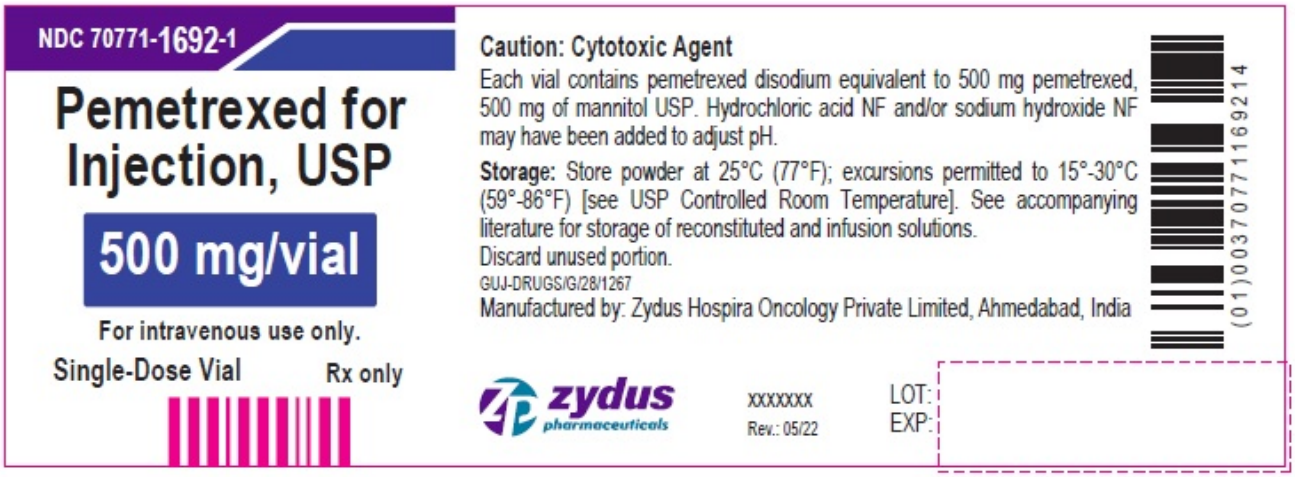
Pemetrexed for Injection, USP

500 mg/vial

For intravenous use only.

Single-Dose Vial

Rx only



NDC 70771-1692-1

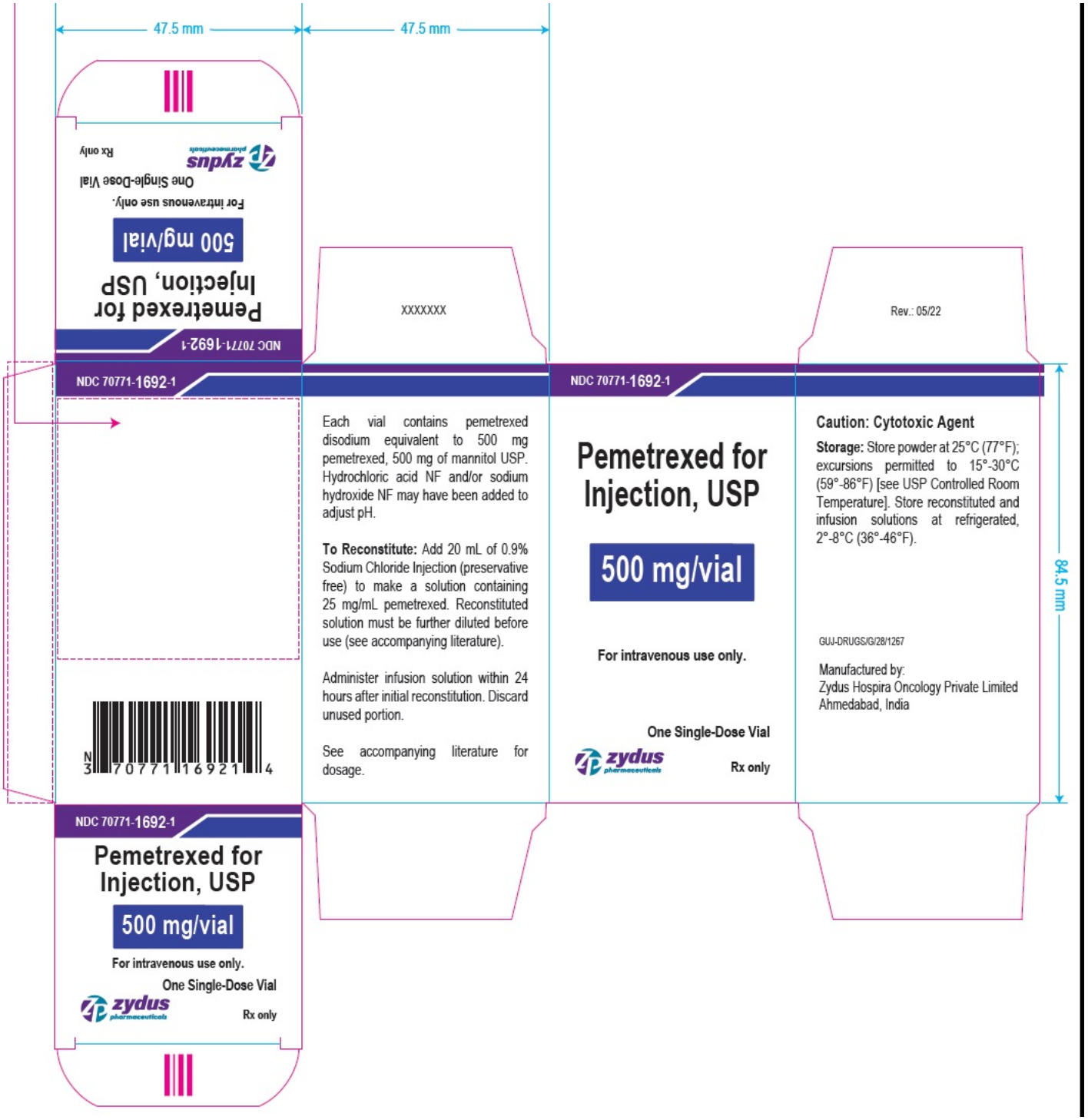
Pemetrexed for Injection, USP

500 mg/vial

For intravenous use only.

One Single-Dose Vial Carton

Rx only



NDC 70771-1693-1

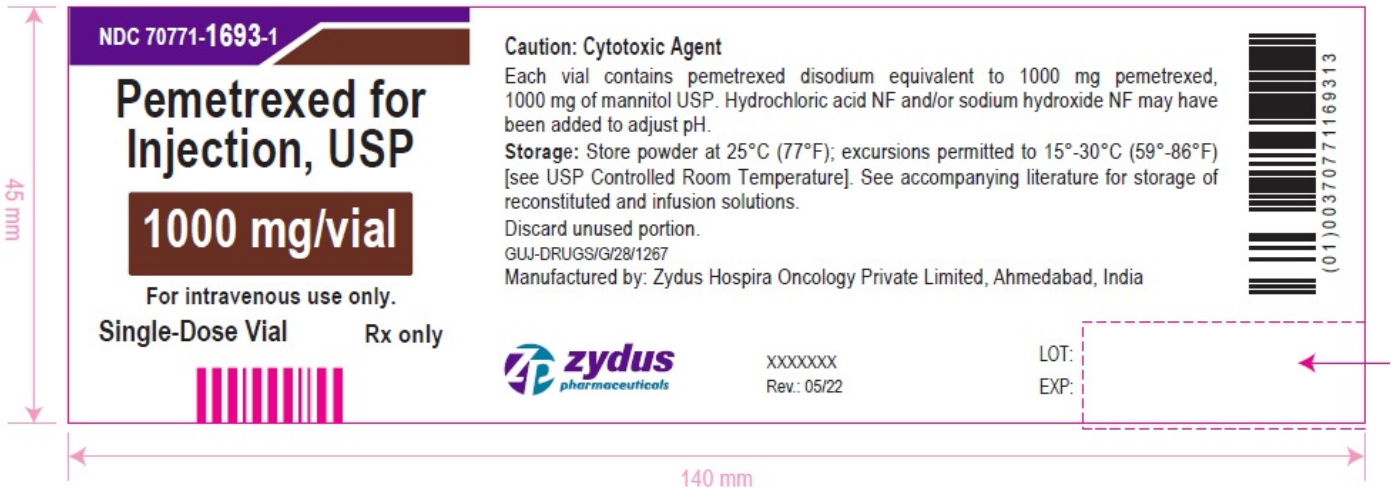
Pemetrexed for Injection, USP

1000 mg/vial

For intravenous use only.

Single-Dose Vial

Rx only



NDC 70771-1693-1

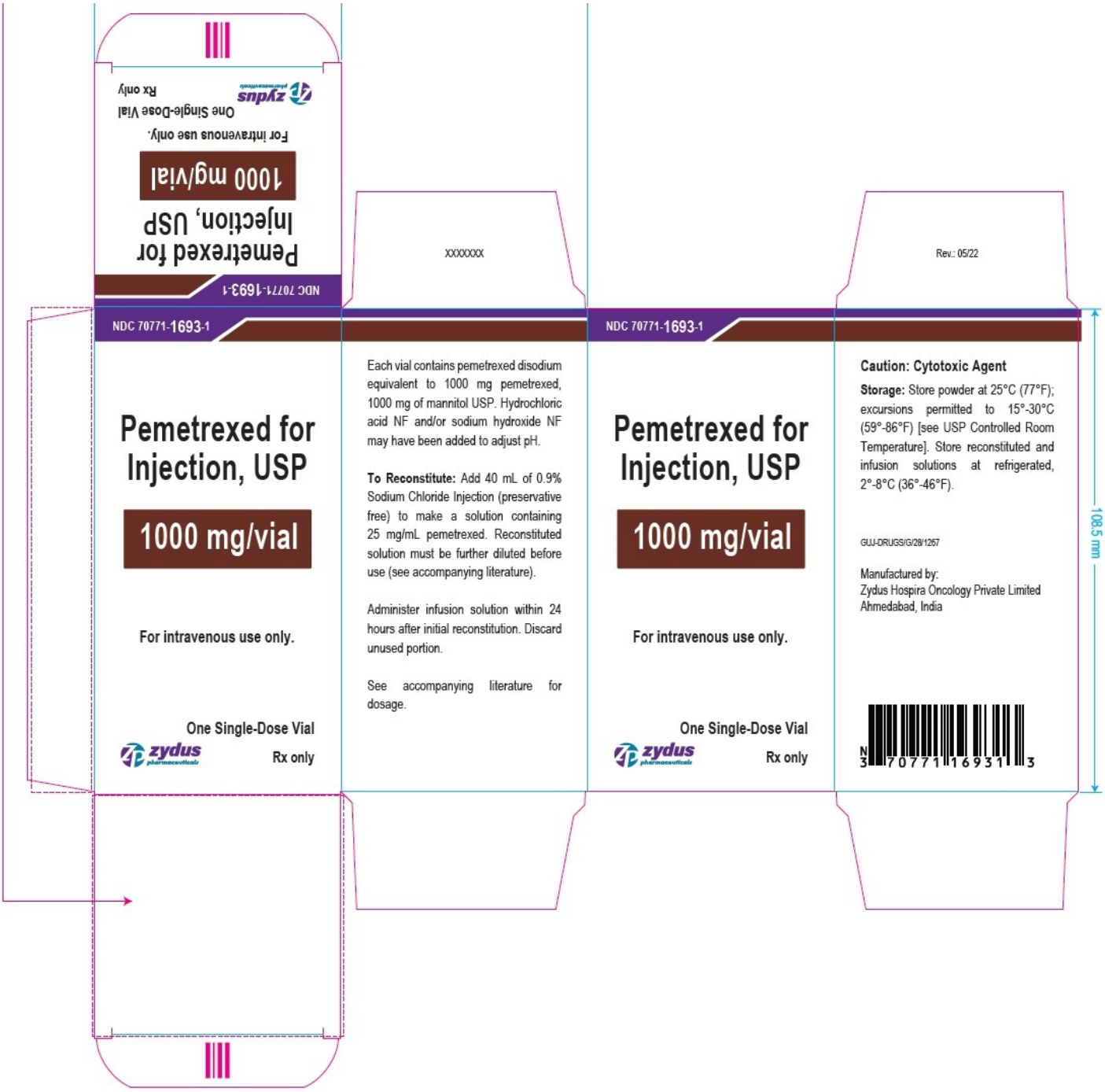
Pemetrexed for Injection, USP

1000 mg/vial

For intravenous use only.

One Single-Dose Vial Carton

Rx only



PEMETREXED

pemetrexed disodium injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1691
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of**	**Strength**

Ingredient Name	Basis of Strength	Strength
PEMETREXED DISODIUM (UNII: 2PKU919BA9) (PEMETREXED - UNII:04Q9AIZ7NO)	PEMETREXED	100 mg in 4 mL

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	106 mg in 4 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1691-1	1 in 1 CARTON	05/26/2022	
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	ANDA214073	05/26/2022	

PEMETREXED

pemetrexed disodium injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1692
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PEMETREXED DISODIUM (UNII: 2PKU919BA9) (PEMETREXED - UNII:04Q9AIZ7NO)	PEMETREXED	500 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	500 mg in 20 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1692-1	1 in 1 CARTON	05/26/2022	
1		20 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	ANDA214073	05/26/2022	

PEMETREXED

pemetrexed disodium injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1693
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PEMETREXED DISODIUM (UNII: 2PKU919BA9) (PEMETREXED - UNII:04Q9AIZ7NO)	PEMETREXED	1000 mg in 40 mL

Inactive Ingredients	
Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	1000 mg in 40 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1693-1	1 in 1 CARTON	05/26/2022	
1		40 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	ANDA214073	05/26/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Hospira Oncology Private Limited		676190889	ANALYSIS(70771-1691, 70771-1692, 70771-1693) , LABEL(70771-1691, 70771-1692, 70771-1693) , MANUFACTURE(70771-1691, 70771-1692, 70771-1693) , PACK(70771-1691, 70771-1692, 70771-1693)

Revised: 5/2022 Zydus Lifesciences Limited