

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.

Single-Dose Vial Rx only

Caution: Cytotoxic Agent

Each vial contains pemetrexed disodium equivalent to 100 mg pemetrexed, 106 mg of mannitol USP. Hydrochloric acid NF and/or sodium hydroxide NF may have been added to adjust pH.

Storage: Store powder at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. See accompanying literature for storage of reconstituted and infusion solutions.

Discard unused portion.

GUJ-DRUGS/G/28/1267

Manufactured by: Zydus Hospira Oncology Private Limited, Ahmedabad, India

XXXXXXXX Rev.: 05/22

LOT: _____

EXP: _____

(01) 00370771169115

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.

Single-Dose Vial Rx only



Caution: Cytotoxic Agent


Each vial contains pemetrexed disodium equivalent to 500 mg pemetrexed, 500 mg of mannitol USP. Hydrochloric acid NF and/or sodium hydroxide NF may have been added to adjust pH.

Storage: Store powder at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. See accompanying literature for storage of reconstituted and infusion solutions.


Discard unused portion.

GUJ-DRUGS/G/28/1267

Manufactured by: Zydus Hospira Oncology Private Limited, Ahmedabad, India



(01)00370771169214

 **zydus**
pharmaceuticals

XXXXXXX
Rev.: 05/22

LOT:
EXP:

NDC 70771-1692-1

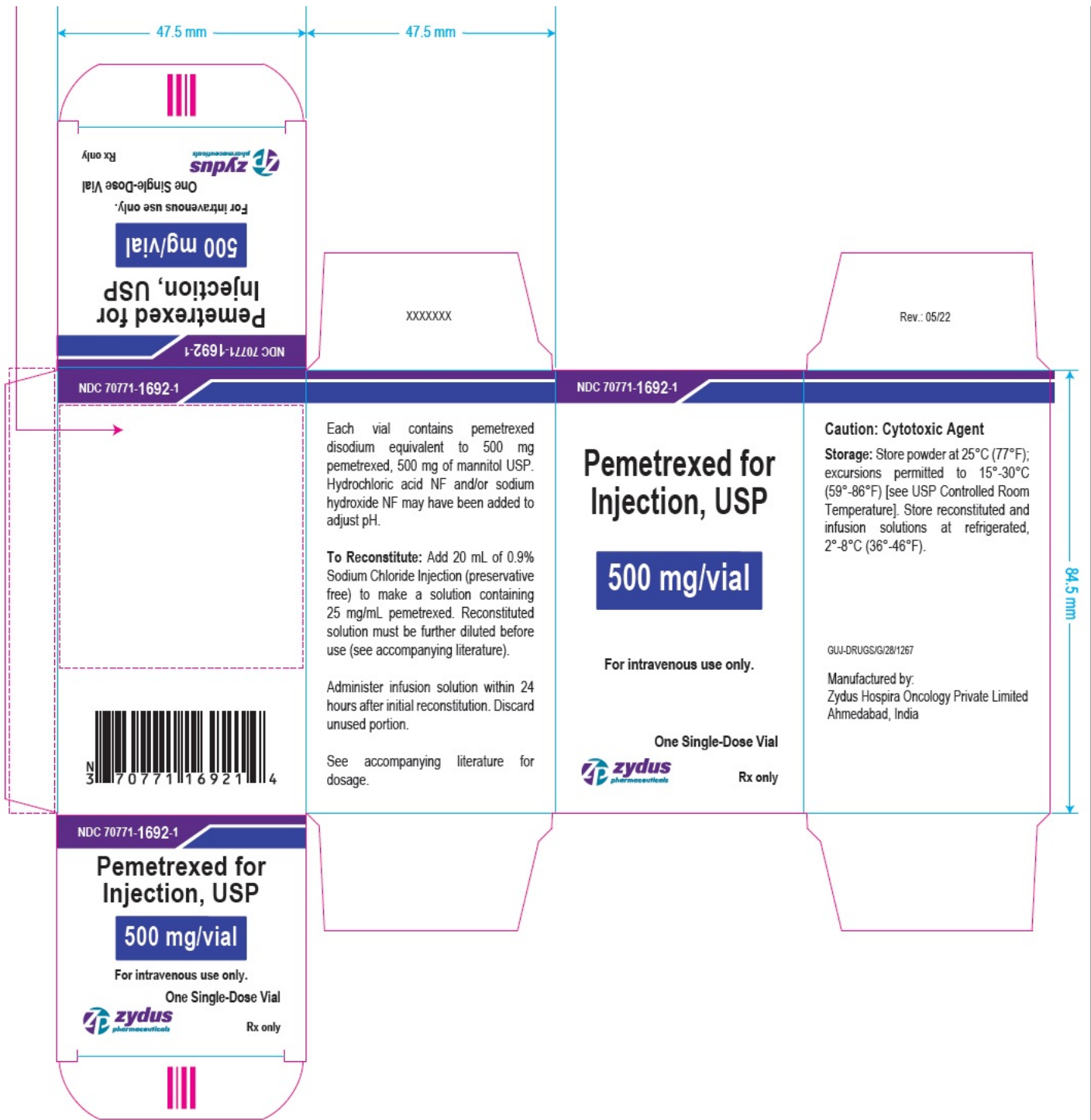
Pemetrexed for Injection, USP

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.

Single-Dose Vial Rx only

Caution: Cytotoxic Agent

Each vial contains pemetrexed disodium equivalent to 1000 mg pemetrexed, 1000 mg of mannitol USP. Hydrochloric acid NF and/or sodium hydroxide NF may have been added to adjust pH.

Storage: Store powder at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. See accompanying literature for storage of reconstituted and infusion solutions.

Discard unused portion.

GUJ-DRUGS/G/28/1267

Manufactured by: Zydus Hospira Oncology Private Limited, Ahmedabad, India

zydus
pharmaceuticals

XXXXXXX
Rev.: 05/22

LOT: _____
EXP: _____

(01)00370771169313

45 mm

140 mm

NDC 70771-1693-1

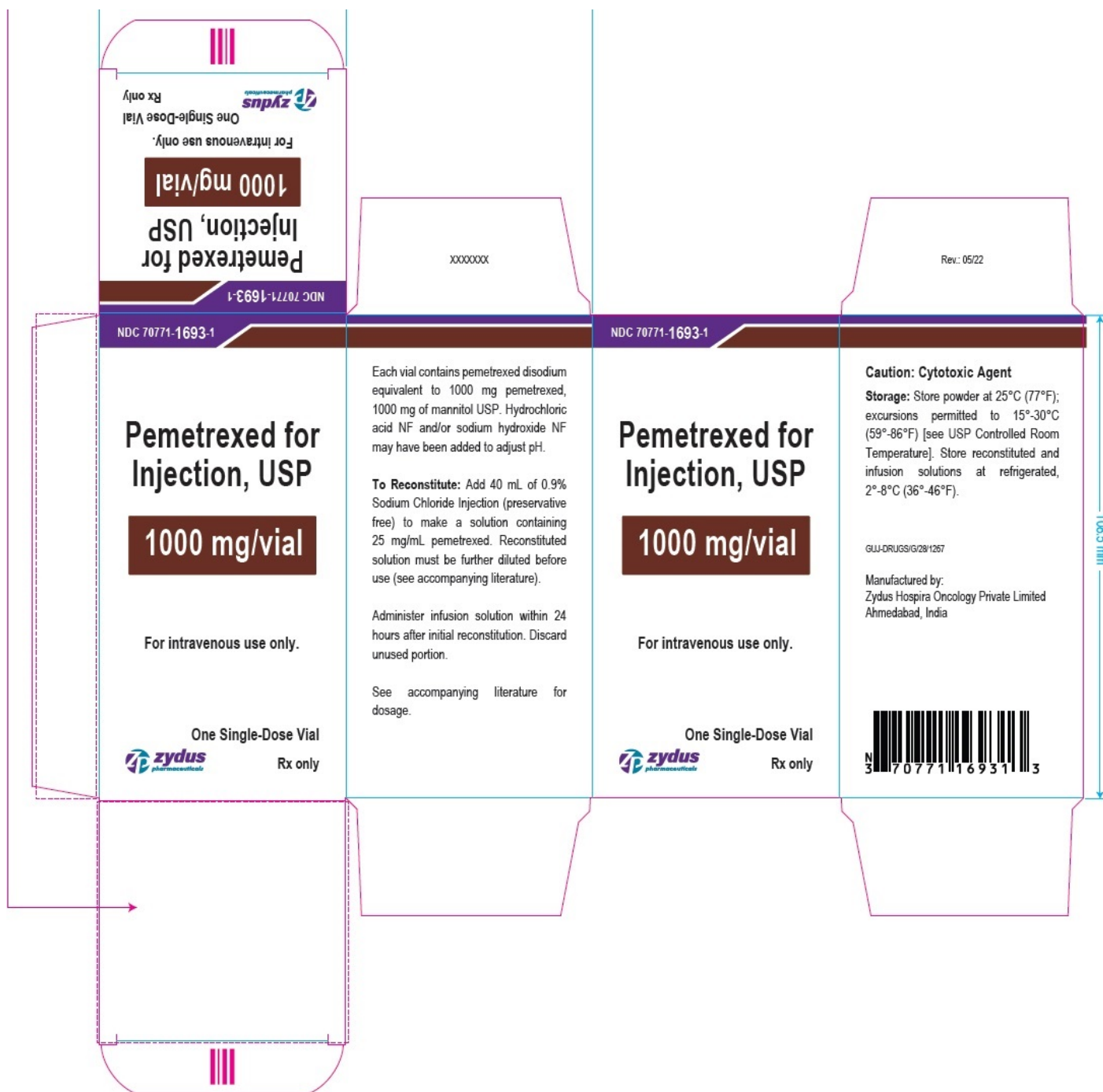
Pemetrexed for Injection, USP

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		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