CYANOCOBALAMIN - cyanocobalamin injection, solution
Zydus Lifesciences Limited

Cyanocobalamin Injection, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1688-1

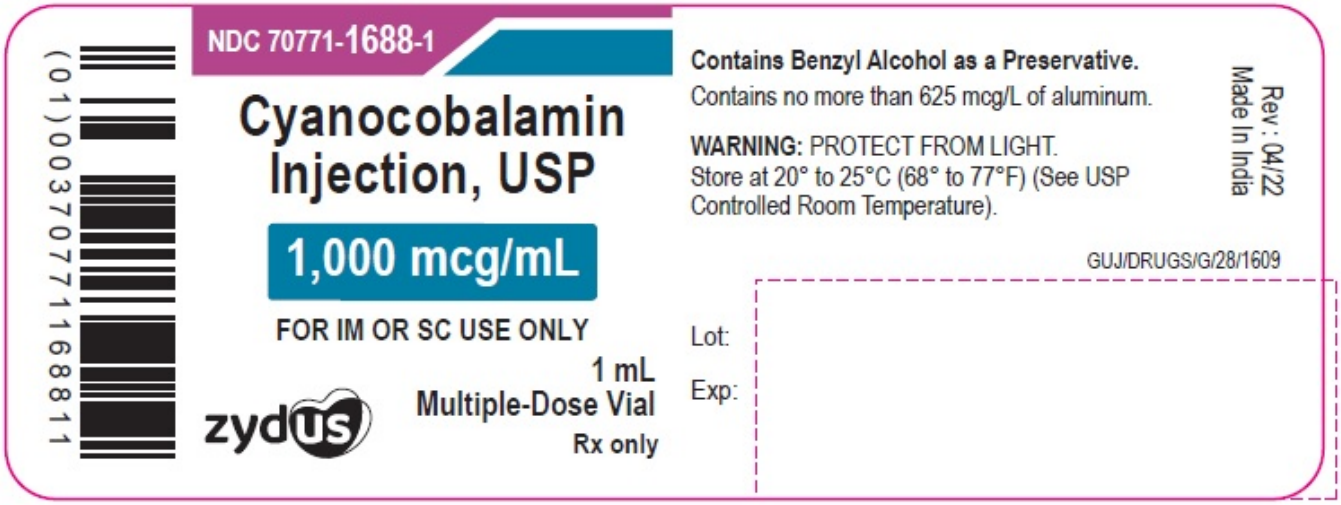
Cyanocobalamin Injection, USP

1,000 mcg/mL

FOR IM OR SC USE ONLY

1 mL Multiple-dose Vial

Rx only



NDC 70771-1668-7

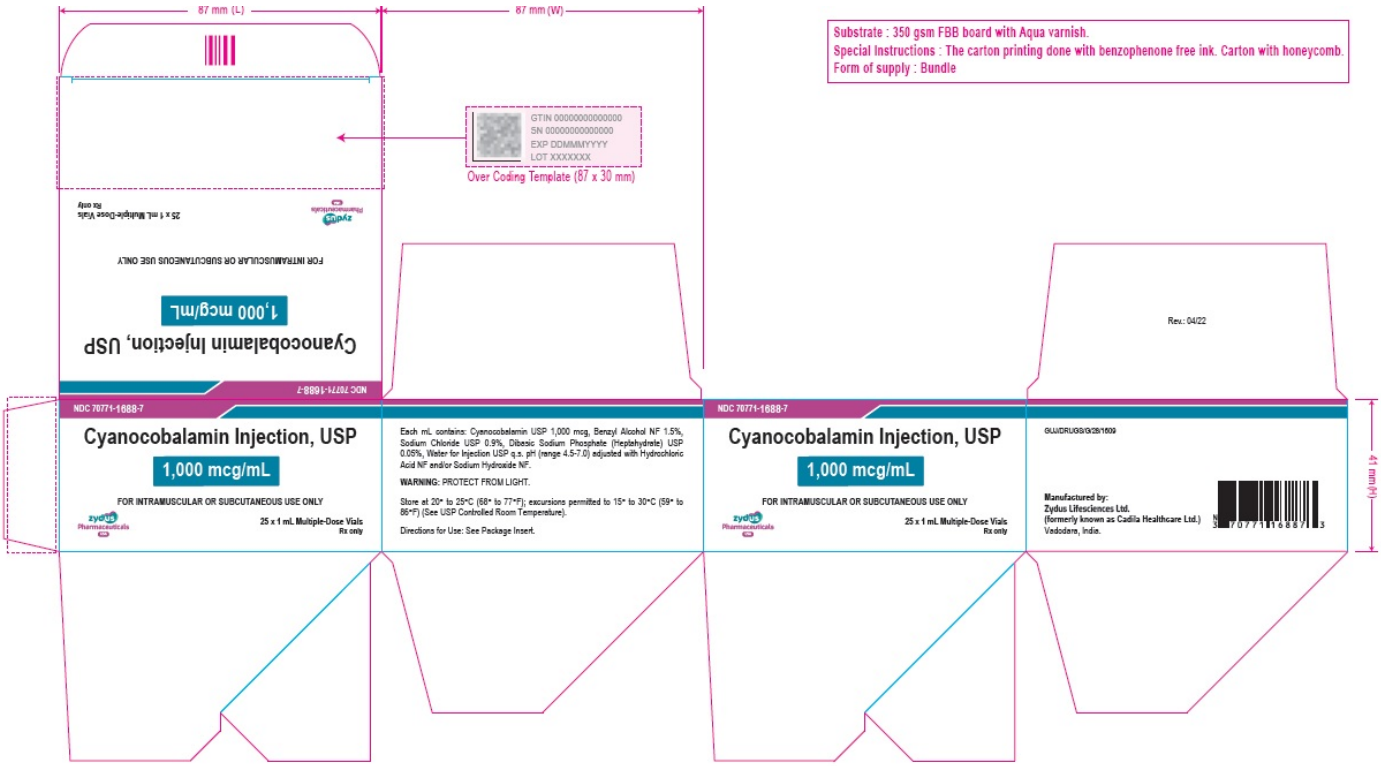
Cyanocobalamin Injection, USP

1,000 mcg/mL

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

25 X 1 mL Multiple-dose Vials

Rx only



NDC 70771-1689-1

Cyanocobalamin Injection, USP

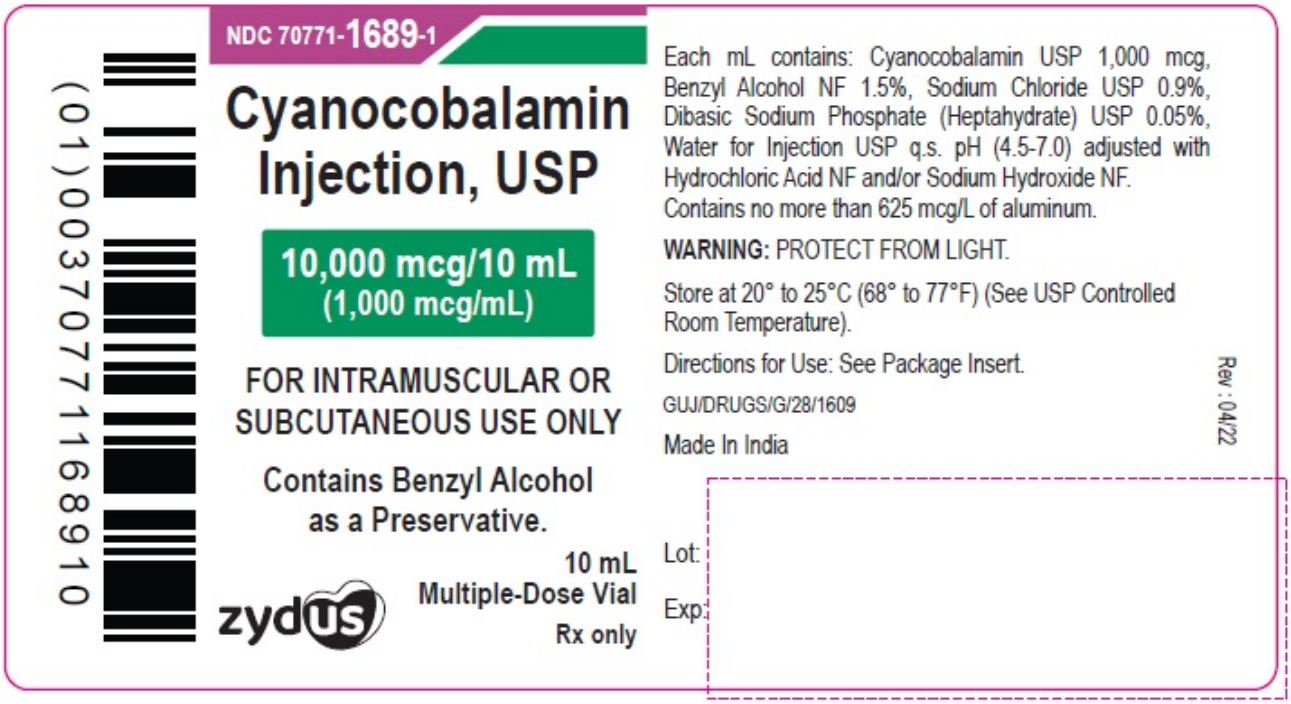
10,000 mcg/10 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

Contains Benzyl Alcohol as a Preservative.

10 mL Multiple-Dose Vial

Rx only



NDC 70771-1689-6

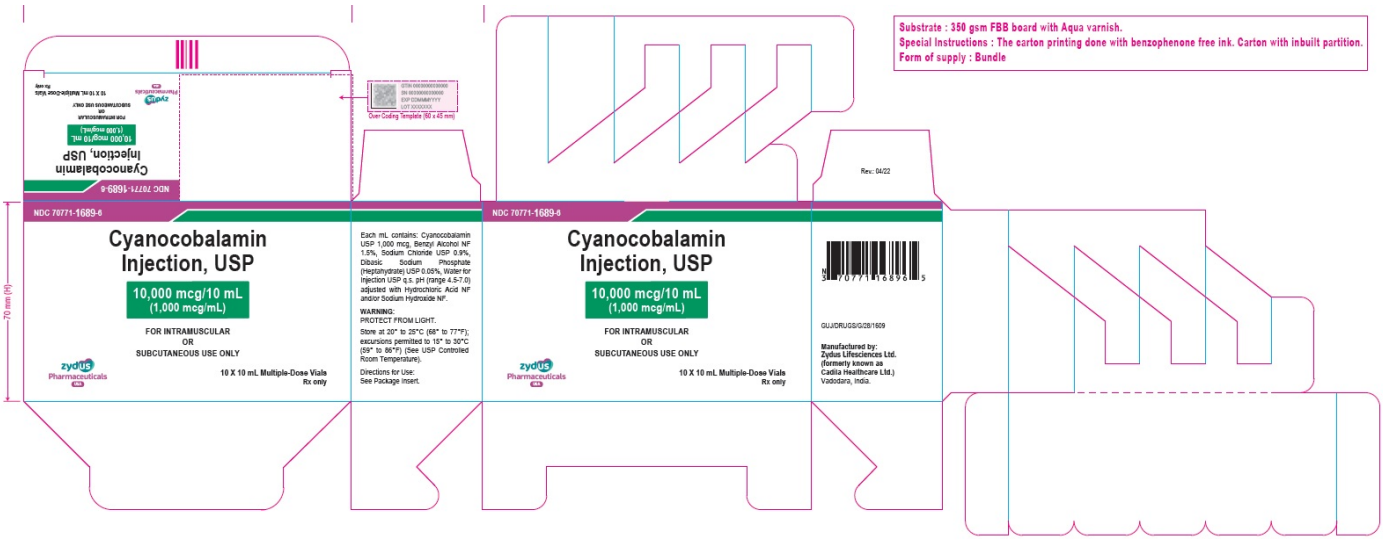
Cyanocobalamin Injection, USP

10,000 mcg/10 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

10 X 10 mL Multiple-Dose Vials

Rx only



NDC 70771-1689-7

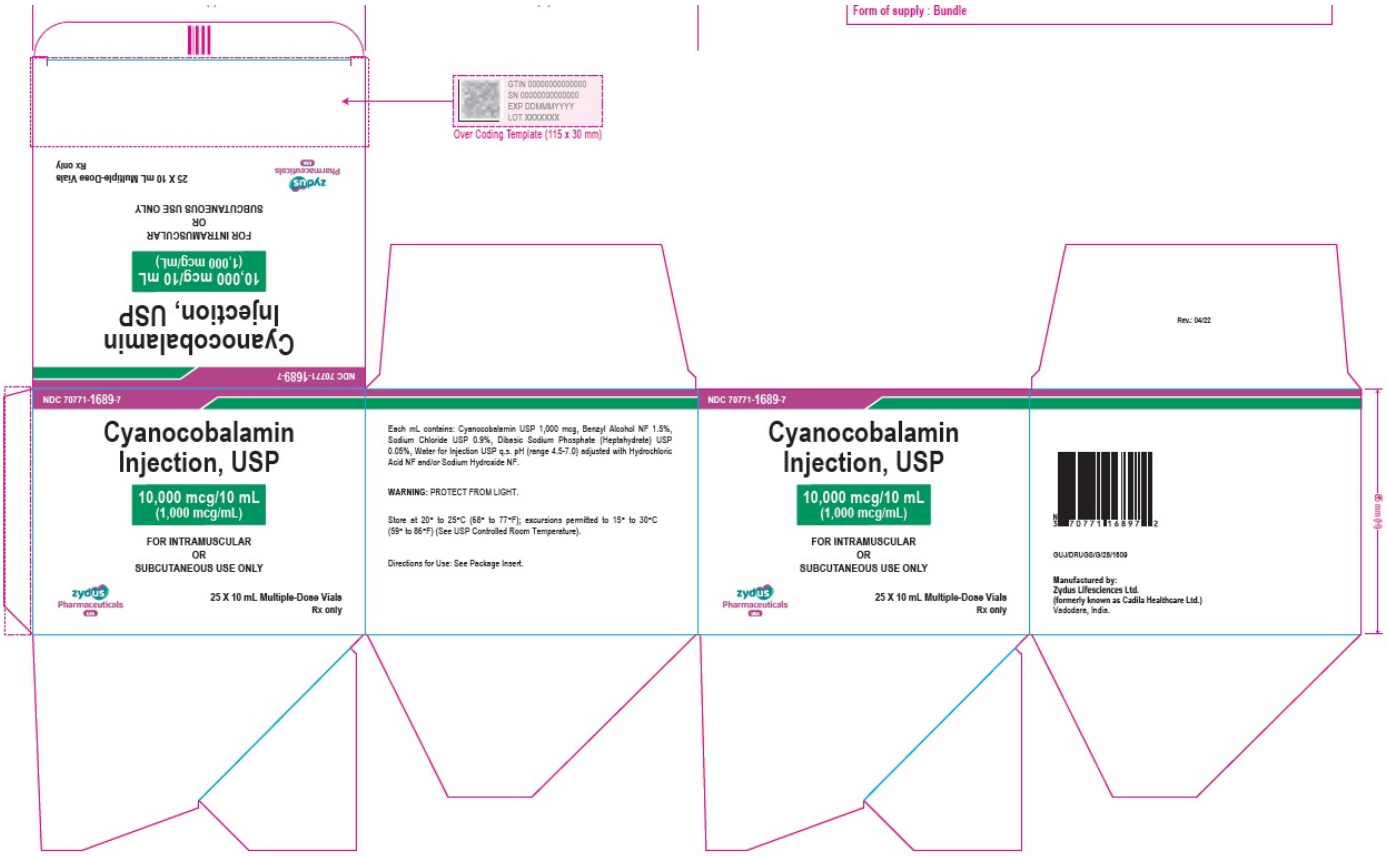
Cyanocobalamin Injection, USP

10,000 mcg/10 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

25 X 10 mL Multiple-Dose Vials

Rx only



NDC 70771-1690-1

Cyanocobalamin Injection, USP

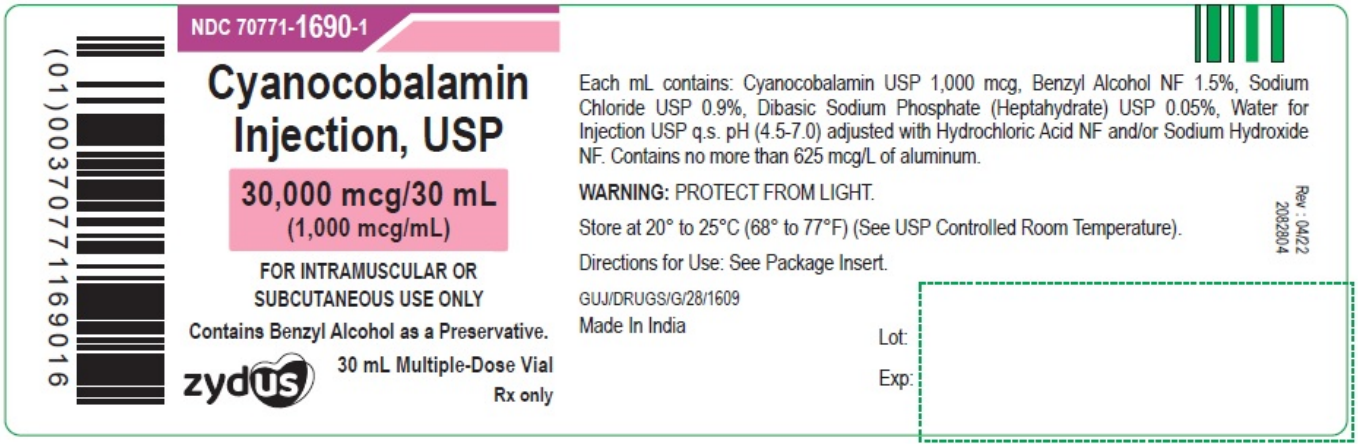
30,000 mcg/30 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

Contains Benzyl Alcohol as a Preservative.

30 mL Multiple-Dose Vial

Rx only



NDC 70771-1690-1

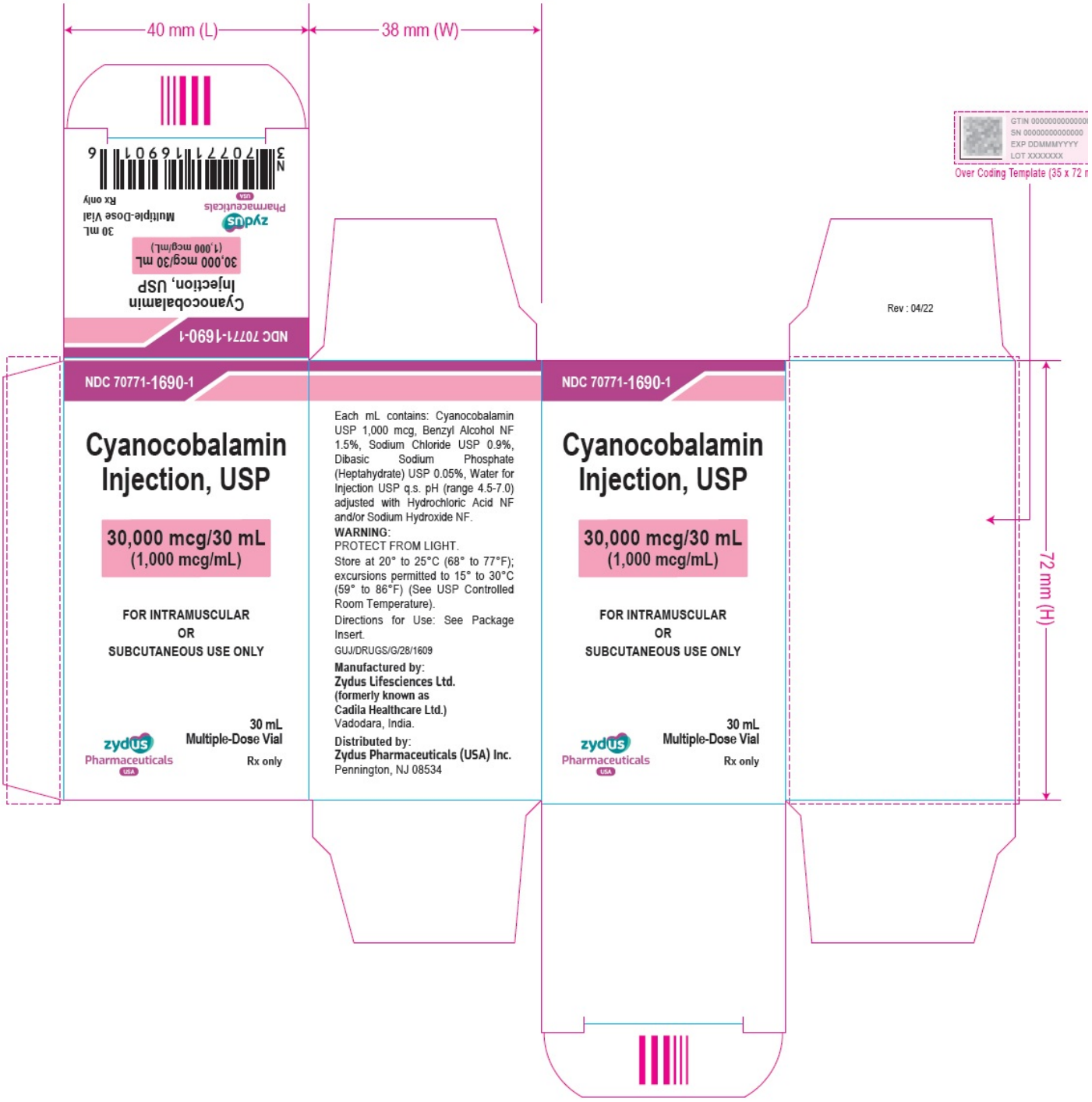
Cyanocobalamin Injection, USP

30,000 mcg/30 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

30 mL Multiple-Dose Vial – Carton Label

Rx only



NDC 70771-1690-5

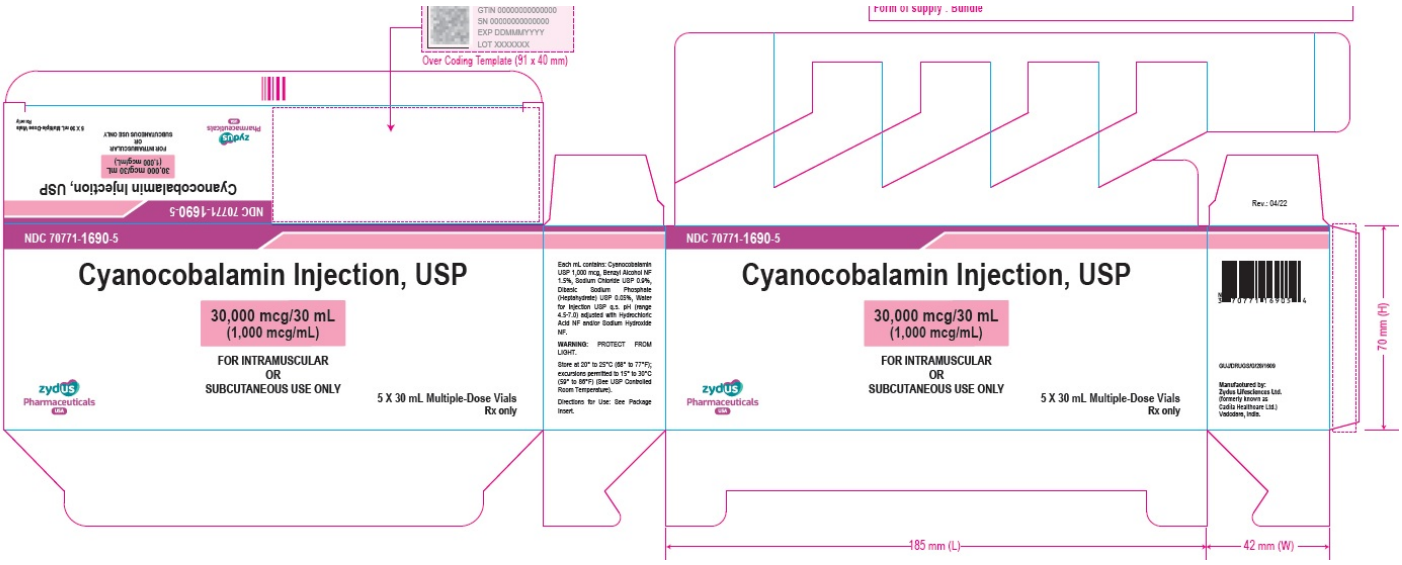
Cyanocobalamin Injection, USP

30,000 mcg/30 mL (1,000 mcg/mL)

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY

5 X 30 mL Multiple-Dose Vials

Rx only



CYANOCOBALAMIN

cyanocobalamin injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1688
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	1000 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1688-7	25 in 1 VIAL	05/05/2022	
1	NDC:70771-1688-1	1 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214655	05/05/2022	

CYANOCOBALAMIN

cyanocobalamin injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1689
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	1000 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1689-6	10 in 1 VIAL	05/05/2022	
1	NDC:70771-1689-1	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1689-7	25 in 1 CARTON	05/05/2022	
2		10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA214655	05/05/2022	

CYANOCOBALAMIN

cyanocobalamin injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1690
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	1000 ug in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1690-1	1 in 1 CARTON	05/05/2022	
1		30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1690-5	5 in 1 CARTON	05/05/2022	
2		30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214655	05/05/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1688, 70771-1689, 70771-1690) , ANALYSIS(70771-1688, 70771-1689, 70771-1690)