BORTEZOMIB - bortezomib injection, powder, lyophilized, for solution
Zydus Lifesciences Limited

BORTEZOMIB for injection, for subcutaneous or intravenous use

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1708-1

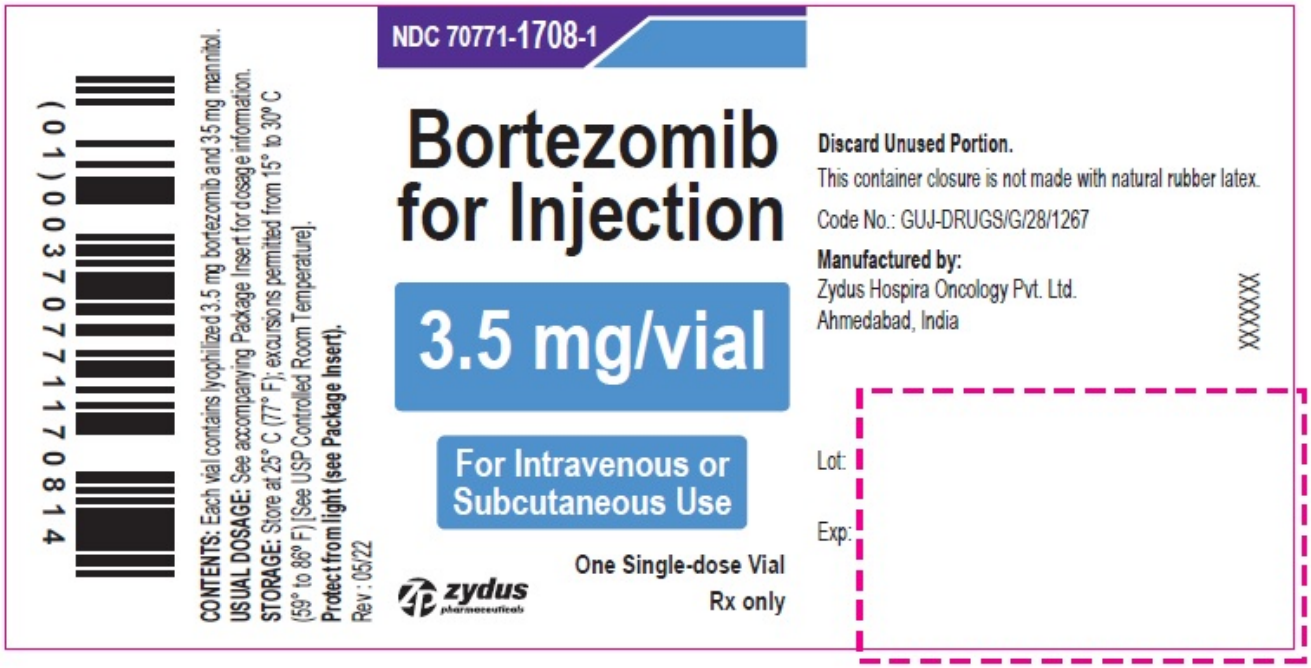
Bortezomib for Injection

3.5 mg/vial

For Intravenous or Subcutaneous Use

One Single-dose Vial

Rx only



NDC 70771-1708-1

Bortezomib for Injection – Carton label

3.5 mg/vial

For Intravenous or Subcutaneous Use

Reconstitution Information

SUBCUTANEOUS INJECTION ONLY

0.9% NaCl

Add

1.4 mL

0.9% Sodium Chloride

To make

2.5 mg/mL

final concentration

INTRAVENOUS INJECTION ONLY

0.9% NaCl

Add

3.5 mL

0.9% Sodium Chloride

To make

1 mg/mL

final concentration

One Single-dose Vial

Rx only

Reconstitution Information – Inside Flap (All cartons)

SUBCUTANEOUS INJECTION ONLY

0.9% NaCl

Add

1.4 mL

0.9% Sodium Chloride

To make

2.5 mg/mL

final concentration

INTRAVENOUS INJECTION ONLY

0.9% NaCl

Add

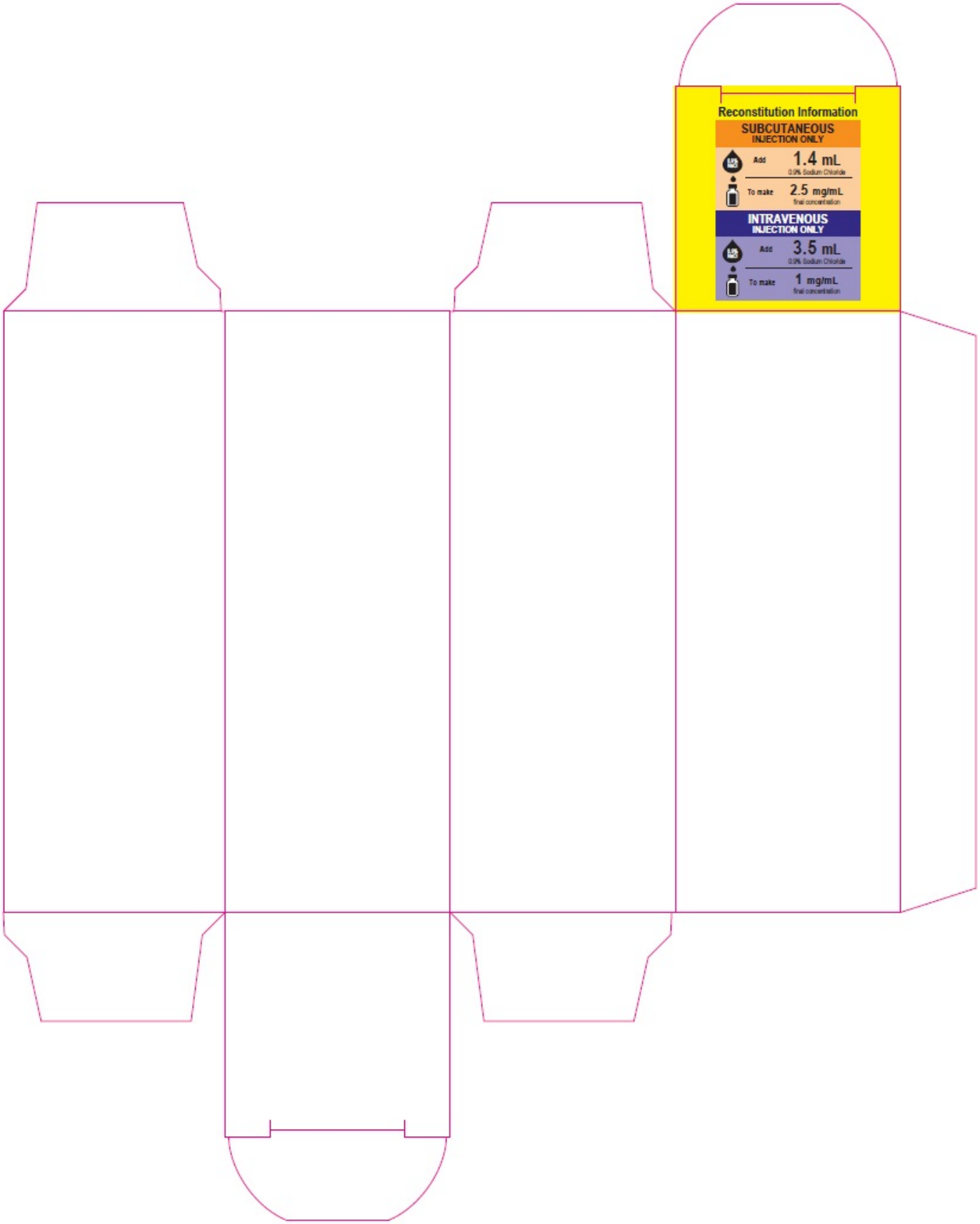
3.5 mL

0.9% Sodium Chloride

To make

1 mg/mL

final concentration



BORTEZOMIB

bortezomib injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1708
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BORTEZOMIB (UNII: 69G8BD63PP) (BORTEZOMIB - UNII:69G8BD63PP)	BORTEZOMIB	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1708-1	1 in 1 CARTON	05/02/2022	
1		3.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210204	05/02/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Hospira Oncology Private Limited		676190889	ANALYSIS(70771-1708) , LABEL(70771-1708) , MANUFACTURE(70771-1708) , PACK(70771-1708)

Revised: 5/2022 Zydus Lifesciences Limited