

NITROGLYCERIN - nitroglycerin tablet
Zydus Lifesciences Limited

Nitroglycerin Sublingual Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1717-1

Nitroglycerin Sublingual Tablets, USP 0.3 mg

Rx only

100 Tablets

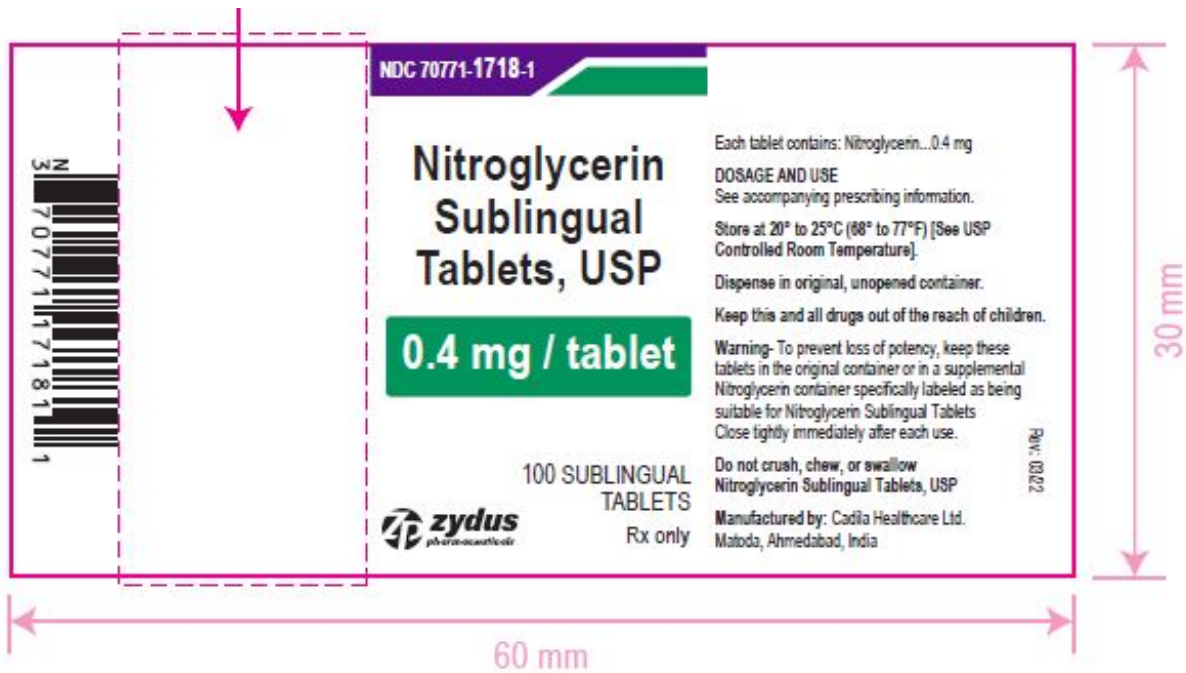


NDC 70771-1718-1

Nitroglycerin Sublingual Tablets 0.4 mg

Rx only

100 Tablets



NDC 70771-1719-1

Nitroglycerin Sublingual Tablets 0.6 mg

Rx only

100 Tablets



NITROGLYCERIN

nitroglycerin tablet

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1717	
Route of Administration	SUBLINGUAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	0.3 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	CALCIUM STEARATE (UNII: 776XM7047L)			
	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics				
Color	WHITE (OFF WHITE)	Score	no score	
Shape	ROUND	Size	4mm	
Flavor		Imprint Code	3;T	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1717-1	1 in 1 CARTON	02/02/2023	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210153	02/02/2023		

NITROGLYCERIN			
nitroglycerin tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1718
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	0.4 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (OFF WHITE)	Score	no score
Shape	ROUND	Size	4mm
Flavor		Imprint Code	4;T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1718-1	1 in 1 CARTON	02/02/2023	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1718-4	4 in 1 CARTON	02/02/2023	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210153	02/02/2023	

NITROGLYCERIN

nitroglycerin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1719
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGLYCERIN (UNII: G59M7S0W53) (NITROGLYCERIN - UNII:G59M7S0W53)	NITROGLYCERIN	0.6 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (OFF WHITE)	Score	no score
Shape	ROUND	Size	4mm
Flavor		Imprint Code	6;T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1719-1	1 in 1 CARTON	02/02/2023	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210153	02/02/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1717, 70771-1718, 70771-1719) , MANUFACTURE(70771-1717, 70771-1718, 70771-1719)