THEOPHYLLINE- theophylline tablet, extended release Zydus Lifesciences Limited

Theophylline Extended-Release Tablets

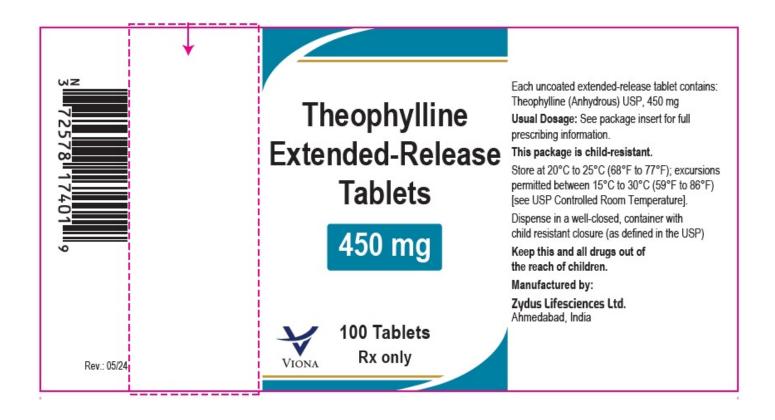
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Theophylline extended-release tablets, 300 mg 100 Tablets
NDC 70771-1782-1

Rx only



Theophylline extended-release tablets, 450 mg 100 Tablets
NDC 70771-1783-1
Rx only



THEOPHYLLINE

theophylline tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1782
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
THEOPHYLLINE ANHYDROUS (UNII: 0155128JYK) (THEOPHYLLINE ANHYDROUS - UNII: 0155128JYK)	THEOPHYLLINE ANHYDROUS	300 mg	

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	WHITE (off white)	Score	2 pieces
Shape	CAPSULE (biconvex)	Size	14mm
Flavor		Imprint Code	7;28
Contains			

Pack	caging			
# It	em Code	Package Description	Marketing Start Date	Marketing End Date
1 ND0	C:70771- 32-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA218063	05/25/2024		

THEOPHYLLINE

theophylline tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1783
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
THEOPHYLLINE ANHYDROUS (UNII: 0155128JYK) (THEOPHYLLINE ANHYDROUS - UNII: 0155128JYK)	THEOPHYLLINE ANHYDROUS	450 mg	

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ 989GH94E)	

Product Characteristics				
Color	WHITE (off white)	Score	2 pieces	
Shape	CAPSULE (biconvex)	Size	19mm	
Flavor		Imprint Code	7;29	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:70771- 1783-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2024	
Marketing	Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218063	05/25/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1782, 70771-1783), MANUFACTURE(70771-1782, 70771-1783)

Revised: 5/2024 Zydus Lifesciences Limited