

**THEOPHYLLINE- theophylline tablet, extended release**  
**Zydus Lifesciences Limited**

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**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



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17401  
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# Theophylline Extended-Release Tablets

450 mg



**100 Tablets**

**Rx only**

Each uncoated extended-release tablet contains:  
Theophylline (Anhydrous) USP, 450 mg

**Usual Dosage:** See package insert for full  
prescribing information.

**This package is child-resistant.**

Store at 20°C to 25°C (68°F to 77°F); excursions  
permitted between 15°C to 30°C (59°F to 86°F)  
[see USP Controlled Room Temperature].

Dispense in a well-closed, container with  
child resistant closure (as defined in the USP)

**Keep this and all drugs out of  
the reach of children.**

**Manufactured by:**  
**Zydus Lifesciences Ltd.**  
Ahmedabad, India

Rev.: 05/24

## THEOPHYLLINE

## Product Information

### Active Ingredient/Active Moiety

## Inactive Ingredients

## Product Characteristics

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1782-1	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: 0I55128JYK) (THEOPHYLLINE ANHYDROUS - UNII:0I55128JYK)	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: FZ989GH94E)	

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)