

BENZONATATE- benzonatate capsule
Zydus Lifesciences Limited

Benzonatate Capsules, USP

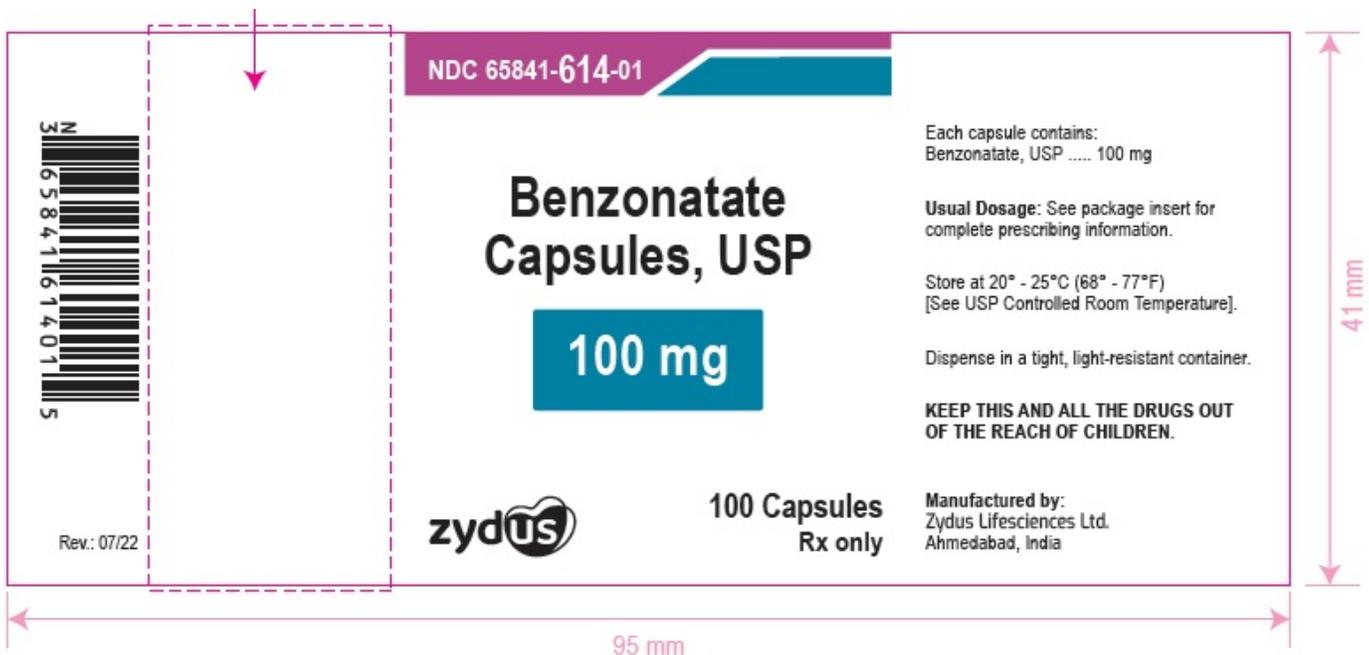
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-614-01 in bottle of 100 capsules

Benzonatate Capsules USP, 100 mg

R_x only

100 capsules

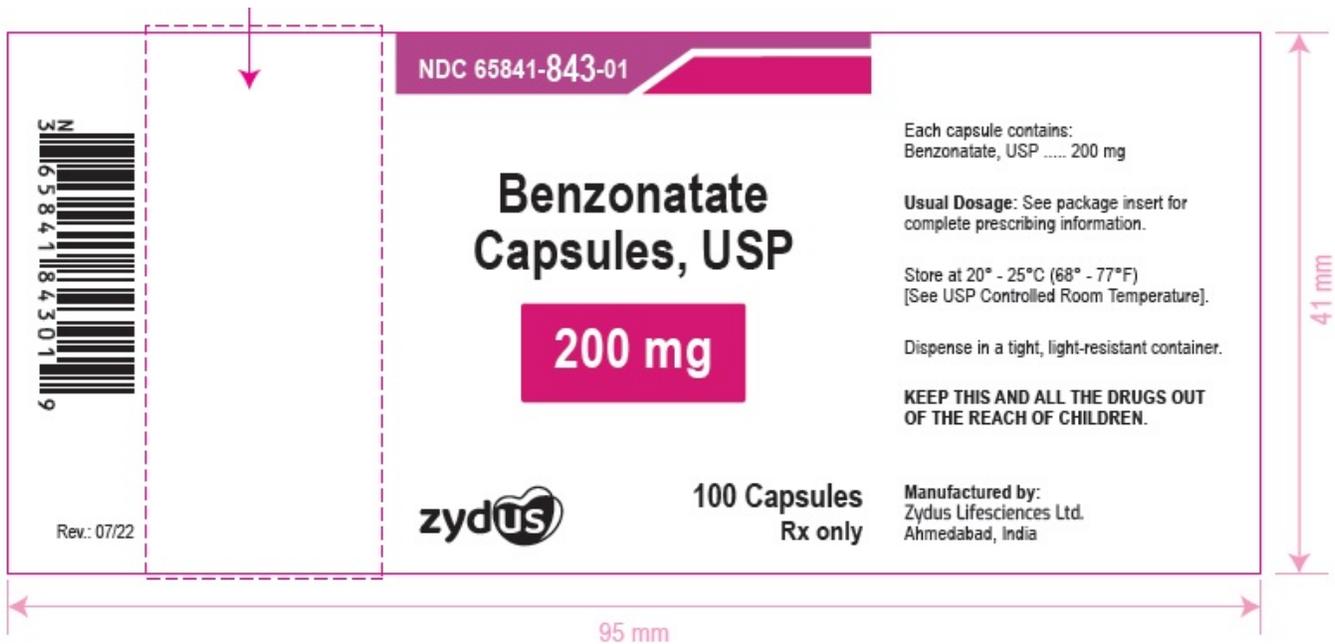


NDC 65841-843-01 in bottle of 100 capsules

Benzonatate Capsules USP, 200 mg

R_x only

100 capsules



BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-614
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZONATATE (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	100 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	3mm
Flavor		Imprint Code	Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-614-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2007	
2	NDC:65841-614-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040597	09/04/2007	

BENZONATATE

benzonatate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-843
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZONATATE (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	OVAL (Oval)	Size	6mm
Flavor		Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-843-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040597	09/04/2007	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-614, 65841-843) , MANUFACTURE(65841-614, 65841-843)

Revised: 11/2024

Zydus Lifesciences Limited