PRUCALOPRIDE- prucalopride tablet, film coated
Zydus Lifesciences Limited

PRUCALOPRIDE tablets, for oral use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

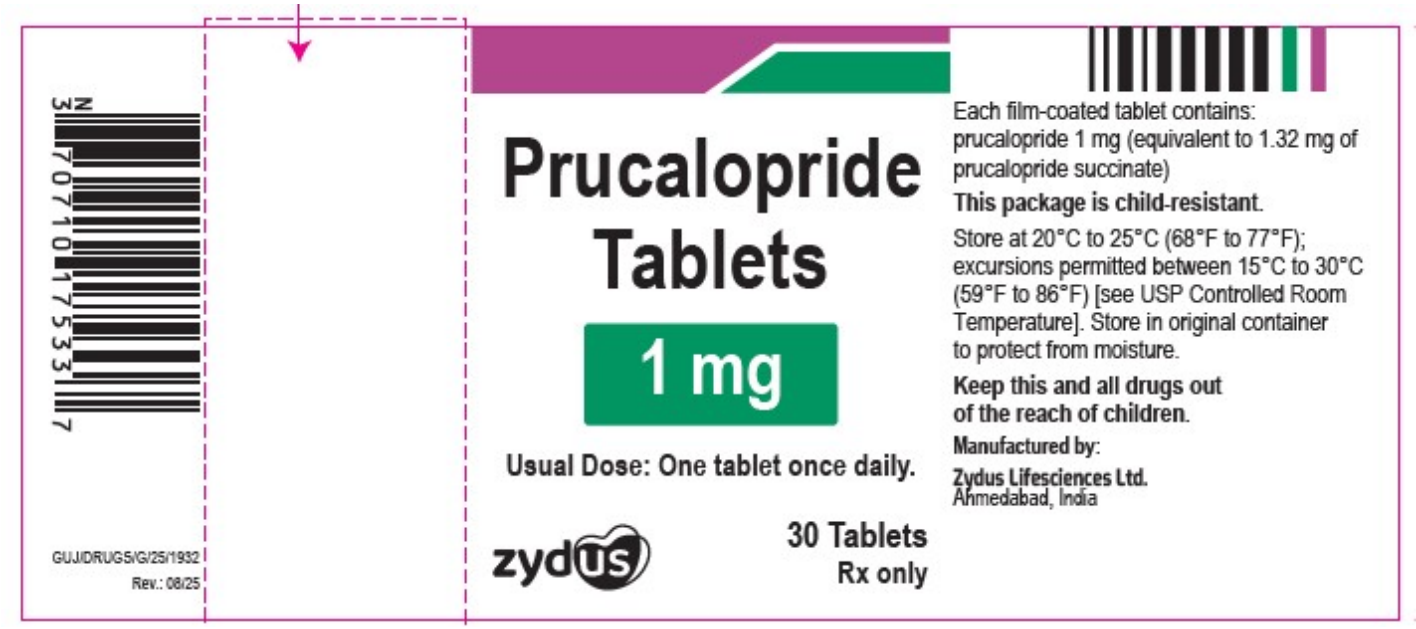
NDC 70771-1899-3

Prucalopride Tablets

1 mg tablet

30 Tablets

Rx only



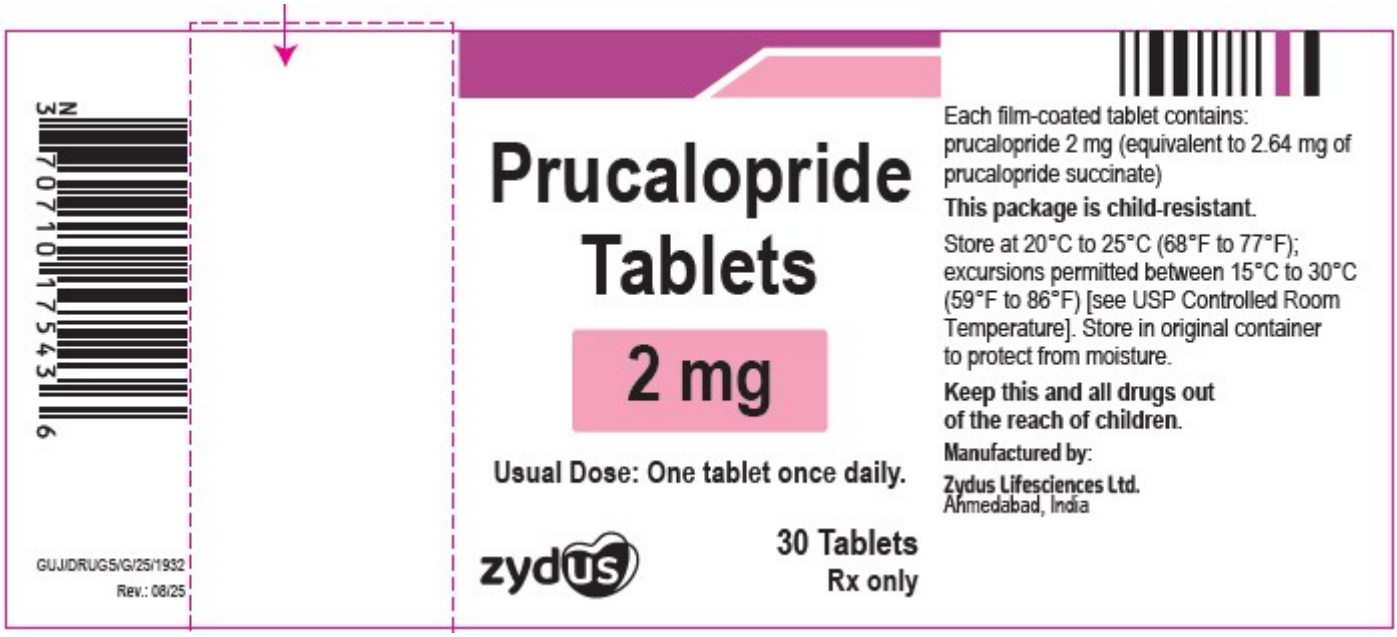
NDC 70771-1900-3

Prucalopride Tablets

2 mg tablet

30 Tablets

Rx only



PRUCALOPRIDE

prucalopride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1899
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRUCALOPRIDE SUCCINATE (UNII: 4V2G75E1CK) (PRUCALOPRIDE - UNII:0A09IUW5TP)	PRUCALOPRIDE	1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	WHITE (Off-white)	**Score**	no score
Shape	ROUND (Round)	**Size**	6mm

Flavor		**Imprint Code**	1753
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1899-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218056	02/02/2026	

PRUCALOPRIDE

prucalopride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1900
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRUCALOPRIDE SUCCINATE (UNII: 4V2G75E1CK) (PRUCALOPRIDE - UNII:0A09IUW5TP)	PRUCALOPRIDE	2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	YELLOW (Light Yellow)	**Score**	no score

Shape	ROUND (Round)	**Size**	9mm
Flavor		**Imprint Code**	1754
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1900-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218056	02/02/2026	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1899, 70771-1900) , MANUFACTURE(70771-1899, 70771-1900)

Revised: 1/2026 Zydus Lifesciences Limited