

PRUCALOPRIDE- prucalopride tablet, film coated
Zydus Lifesciences Limited

PRUCALOPRIDE tablets, for oral use

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

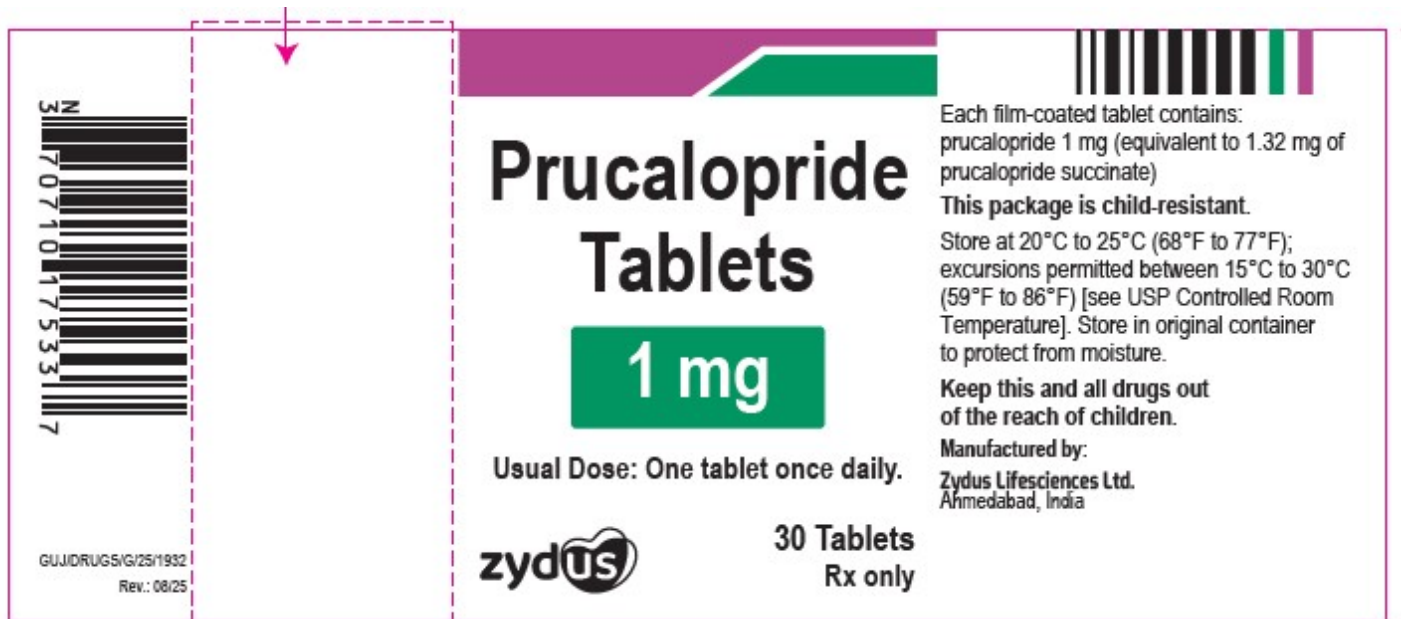
NDC 70771-1899-3

Prucalopride Tablets

1 mg tablet

30 Tablets

Rx only



NDC 70771-1900-3

Prucalopride Tablets

2 mg tablet

30 Tablets

Rx only

GUJIDRUGS/G/25/1932
Rev.: 08/25

**Prucalopride
Tablets**

2 mg

Usual Dose: One tablet once daily.

zydus

Each film-coated tablet contains:
prucalopride 2 mg (equivalent to 2.64 mg of
prucalopride succinate)
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]. Store in original container
to protect from moisture.
Keep this and all drugs out
of the reach of children.
Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

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: 3WJQ0SDW1A)	
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: 3WJQ0SDW1A)			
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)