

**DAPAGLIFLOZIN- dapagliflozin tablet**  
**Zydus Lifesciences Limited**

**Dapagliflozin Tablets**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Dapagliflozin Tablets, 5 mg

NDC 70771-1714-3

Bottles of 30 tablets

Rx only



Dapagliflozin Tablets, 10 mg

NDC 70771-1715-3

Bottles of 30 tablets

Rx only

**Dapagliflozin Tablets**  
**10 mg**

**PHARMACIST:** Dispense the Medication Guide provided separately to each patient.

**zydus** 30 Tablets Rx only

Each film-coated tablet contains 10 mg of dapagliflozin.  
**Recommended Dosage:** See prescribing information.  
**Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].**  
**Keep this and all drugs out of the reach of children.**  
This package is child resistant.  
**Do not use if printed inner seal of bottle is broken or missing.**  
Medication Guide available at [www.zydususa.com/medguides](http://www.zydususa.com/medguides) or call 1-877-993-8779.  
Manufactured by:  
Zydus Lifesciences Ltd., Ahmedabad, India

Rev.: 04/26

## DAPAGLIFLOZIN

dapagliflozin tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1714
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DAPAGLIFLOZIN</b> (UNII: 1ULL0QJ8UC) (DAPAGLIFLOZIN - UNII:1ULL0QJ8UC)	DAPAGLIFLOZIN	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm

<b>Flavor</b>		<b>Imprint Code</b>	1380
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1714-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2026	
2	NDC:70771-1714-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2026	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211582	04/06/2026	

## DAPAGLIFLOZIN

dapagliflozin tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1715
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DAPAGLIFLOZIN</b> (UNII: 1ULL0QJ8UC) (DAPAGLIFLOZIN - UNII:1ULL0QJ8UC)	DAPAGLIFLOZIN	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	1381
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1715-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2026	
2	NDC:70771-1715-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2026	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211582	04/06/2026	

**Labeler** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1714, 70771-1715) , MANUFACTURE(70771-1714, 70771-1715)

Revised: 4/2026

Zydus Lifesciences Limited