

DAPSONE- dapsonone tablet
Zydus Lifesciences Limited

Dapsonone Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1979-3 in bottle of 30 tablets

Dapsonone Tablets USP, 25 mg

Rx only

30 tablets



NDC 70771-1980-3 in bottle of 30 tablets

Dapsonone Tablets USP, 100 mg

Rx only

30 tablets

DAPSONE

dapsone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1979
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)	DAPSONE	25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE (white to off white)	Score	2 pieces
Shape	ROUND	Size	6mm
Flavor		Imprint Code	1713
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1979-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2026	
2	NDC:70771-1979-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA220103	02/27/2026	

DAPSONE

dapsone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1980
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)	DAPSONE	100 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE (White to off white)	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	1714
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:70771-1980-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2026	
2	NDC:70771-1980-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA220103	02/27/2026	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Pharmaceuticals Limited		650173735	MANUFACTURE(70771-1979, 70771-1980) , ANALYSIS(70771-1979, 70771-1980)

Revised: 2/2026

Zydus Lifesciences Limited