ICOSAPENT ETHYL- icosapent ethyl capsule
Softgel Healthcare Private Limited

ICOSAPENT ETHYL capsules, for oral use

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

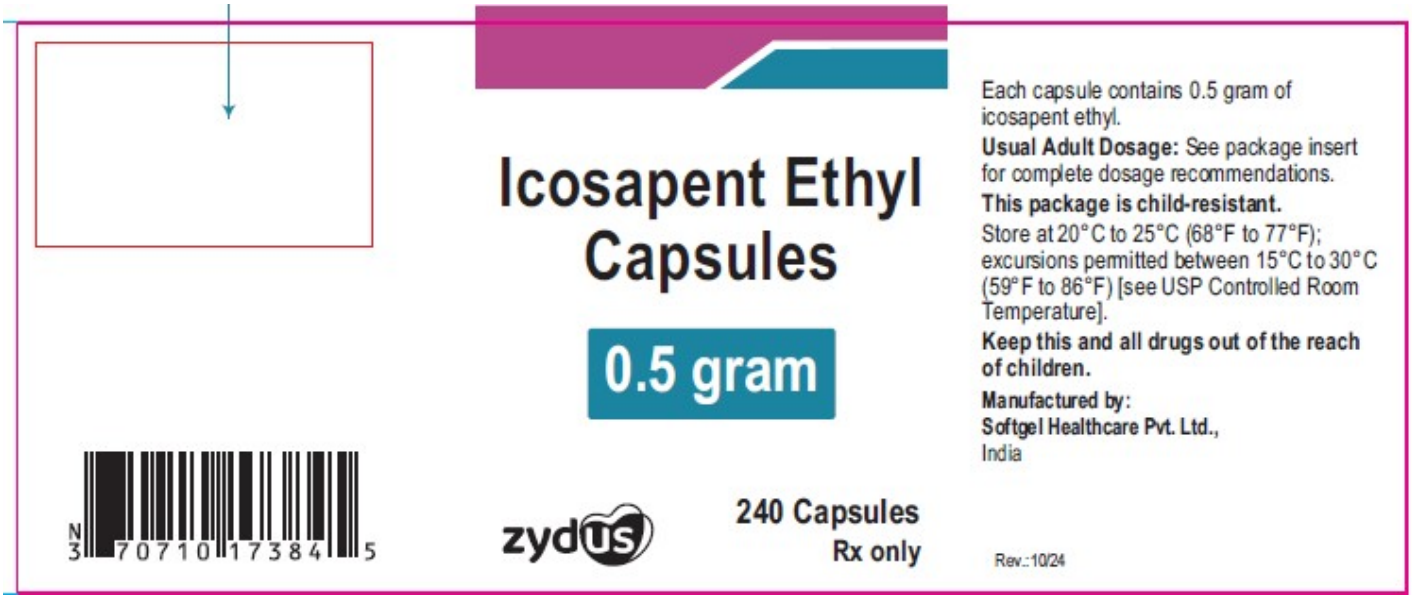
NDC 35916-1738-1

Icosapent Ethyl Capsules

0.5 gram

240 capsules

Rx only



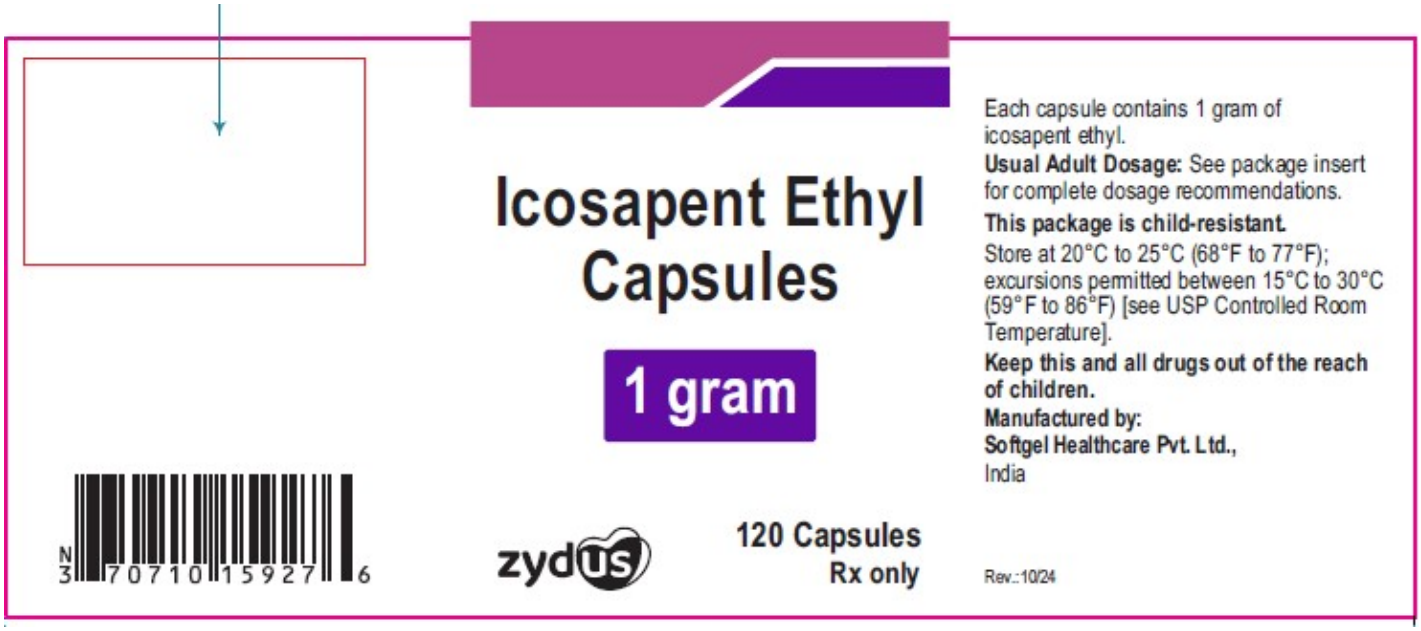
NDC 35916-1592-1

Icosapent Ethyl Capsules

1 gram

240 capsules

Rx only



ICOSAPENT ETHYL

icosapent ethyl capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:35916-1738
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ICOSAPENT ETHYL (UNII: 6GC8A4PAYH) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT ETHYL	0.5 g

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	WHITE (transparent)	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	1738
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-1738-1	240 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217656	03/01/2025	

ICOSAPENT ETHYL

icosapent ethyl capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:35916-1592
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ICOSAPENT ETHYL (UNII: 6GC8A4PAYH) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT ETHYL	1 g

Inactive Ingredients	
Ingredient Name	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	WHITE (transparent)	**Score**	no score
Shape	OVAL (oblong)	**Size**	24mm
Flavor		**Imprint Code**	1592
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-	120 in 1 BOTTLE; Type 0: Not a Combination	03/01/2025	

1	1592-1	Product	03/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217656	03/01/2025	

Labeler - Softgel Healthcare Private Limited (676666501)

Establishment

Name	Address	ID/FEI	Business Operations
Softgel Healthcare Private Limited		676666501	ANALYSIS(35916-1738, 35916-1592) , LABEL(35916-1738, 35916-1592) , MANUFACTURE(35916-1738, 35916-1592) , PACK(35916-1738, 35916-1592)