

**ICOSAPENT ETHYL- icosapent ethyl capsule**  
**Softgel Healthcare Private Limited**

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**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

The image shows the principal display panel for Icosapent Ethyl Capsules. It features a white background with a blue and red header. The product name 'Icosapent Ethyl Capsules' is prominently displayed in black, with '0.5 gram' in a blue box below it. The Zydus logo is at the bottom left, and '240 Capsules Rx only' is at the bottom right. A barcode is located at the bottom left, with the number 'N 31 70710117384 5' below it. On the right side, there is a block of text providing dosage, storage, and safety information. A blue arrow points to a red-outlined box on the left side of the panel.

Each capsule contains 0.5 gram of icosapent ethyl.  
**Usual Adult Dosage:** See package insert for complete dosage recommendations.  
**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].  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
Softgel Healthcare Pvt. Ltd.,  
India

zydus 240 Capsules Rx only

Rev.:10/24

NDC 35916-1592-1

Icosapent Ethyl Capsules

1 gram

240 capsules

Rx only

# Icosapent Ethyl Capsules

1 gram

Each capsule contains 1 gram of icosapent ethyl.

**Usual Adult Dosage:** See package insert for complete dosage recommendations.

**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].

**Keep this and all drugs out of the reach of children.**

**Manufactured by:**  
Softgel Healthcare Pvt. Ltd.,  
India



120 Capsules  
Rx only

Rev.:10/24

## ICOSAPENT ETHYL

icosapent ethyl capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:35916-1738
<b>Route of Administration</b>	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

<b>Color</b>	WHITE (transparent)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	1738
<b>Contains</b>			

## 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	

1592-1	Product	03/01/2025	
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217656	03/01/2025	

**Labeler** - Softgel Healthcare Private Limited (675584180)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Softgel Healthcare Private Limited		675584180	ANALYSIS(35916-1738, 35916-1592) , LABEL(35916-1738, 35916-1592) , MANUFACTURE(35916-1738, 35916-1592) , PACK(35916-1738, 35916-1592)

Revised: 10/2024

Softgel Healthcare Private Limited