

GIALAX- polyethylene glycol 3350
Phlight Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

GIALAX



GIALAX

polyethylene glycol 3350 kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70569-840
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70569-840-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	05/19/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	527 g
Part 2	1 PACKET	3 g in 3

Part 1 of 2

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	1 g in 1 g

Product Characteristics

Color	white (White to Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		527 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076652	10/01/2011	

Part 2 of 2**ALL SPORT MIX**

sport drink mix powder, for solution

Product Information

Route of Administration	ORAL
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Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PIGMENT BLUE 1 (UNII: 4SBE571RQF)	
ASPARTAME (UNII: Z0H242BBR1)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	

CALCIUM SILICATE (UNII: S4255P4G5M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MONOPOTASSIUM PHOSPHITE (UNII: 59RSS63D8J)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BLUEBERRY ("Blue Raz")	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2011	

Labeler - Phlight Pharma, LLC (080168751)

Registrant - Phlight Pharma, LLC (080168751)

Establishment

Name	Address	ID/FEI	Business Operations
Phlight Pharma, LLC		080168751	label(70569-840)