NATEGLINIDE- nateglinide tablet, film coated
Zydus Lifesciences Limited

NATEGLINIDE TABELTS

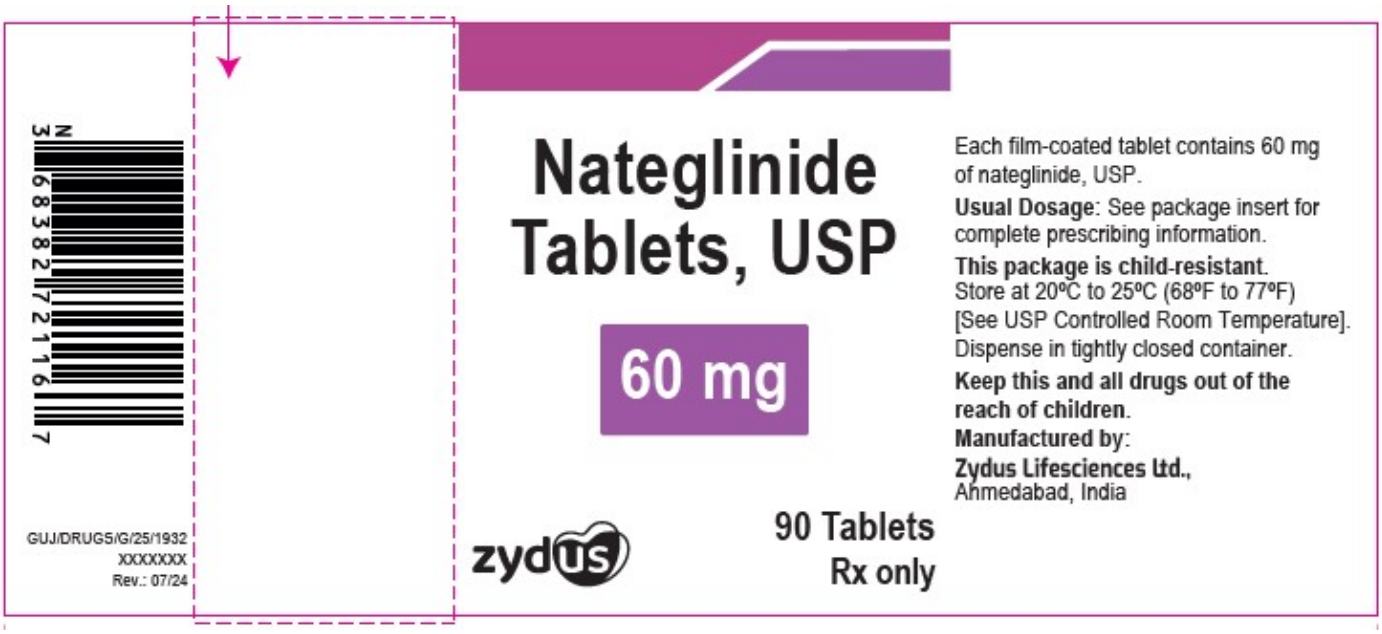
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1015-9 in bottle of 90 tablets

Nateglinide Tablets USP, 60 mg

Rx only

90 tablets



NDC 70771-1016-9 in bottle of 90 tablets

Nateglinide Tablets USP, 120 mg

Rx only

90 tablets

NATEGLINIDE

nateglinide tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1015
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NATEGLINIDE (UNII: 41X3PWK4O2) (NATEGLINIDE - UNII:41X3PWK4O2)	NATEGLINIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	721
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1015-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
2	NDC:70771-1015-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
3	NDC:70771-1015-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
4	NDC:70771-1015-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
5	NDC:70771-1015-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
6	NDC:70771-1015-4	10 in 1 CARTON	10/27/2016	
6	NDC:70771-1015-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205248	10/27/2016	

NATEGLINIDE

nateglinide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NATEGLINIDE (UNII: 41X3PWK4O2) (NATEGLINIDE - UNII:41X3PWK4O2)	NATEGLINIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (LIGHT ORANGE TO ORANGE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	18mm
Flavor		**Imprint Code**	722
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1016-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
2	NDC:70771-1016-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
3	NDC:70771-1016-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
4	NDC:70771-1016-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
5	NDC:70771-1016-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2016	
6	NDC:70771-1016-4	10 in 1 CARTON	10/27/2016	
6	NDC:70771-1016-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205248	10/27/2016	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1015, 70771-1016) , MANUFACTURE(70771-1015, 70771-1016)