IBUPROFEN- ibuprofen tablet, film coated
Bryant Ranch Prepack

IBUPROFEN 400 MG - 600 MG AND 800 MG TABLETS

ibuprofen tablets 400 mg - 600 mg- 800 mg medguide

HOW SUPPLIED

Product: 71335-1396
NDC: 71335-1396-0 84 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-1 20 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-2 15 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-3 40 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-4 21 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-5 30 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-6 90 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-7 100 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-8 120 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1396-9 60 TABLET, FILM COATED in a BOTTLE
Product: 71335-1503
NDC: 71335-1503-0 21 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-1 20 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-2 15 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-3 30 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-4 40 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-5 60 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-6 90 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-7 120 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-8 50 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1503-9 100 TABLET, FILM COATED in a BOTTLE
Product: 71335-1517
NDC: 71335-1517-1 20 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1517-2 30 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1517-3 40 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1517-4 60 TABLET, FILM COATED in a BOTTLE
NDC: 71335-1517-5 90 TABLET, FILM COATED in a BOTTLE

NDC: 71335-1517-6 120 TABLET, FILM COATED in a BOTTLE

NDC: 71335-1517-7 100 TABLET, FILM COATED in a BOTTLE

NDC: 71335-1517-8 21 TABLET, FILM COATED in a BOTTLE

NDC: 71335-1517-9 15 TABLET, FILM COATED in a BOTTLE

Ibuprofen 800mg Tablet

Ibuprofen 600mg Tablet

Ibuprofen 400mg Tablet

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71335-1396(NDC:49483-604)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	800 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	123
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1396-0	84 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
2	NDC:71335-1396-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
3	NDC:71335-1396-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
4	NDC:71335-1396-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
5	NDC:71335-1396-4	21 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
6	NDC:71335-1396-5	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
7	NDC:71335-1396-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
8	NDC:71335-1396-7	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
9	NDC:71335-1396-8	120 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
10	NDC:71335-1396-9	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71335-1503(NDC:49483-603)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	600 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	Score	no score

Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1503-0	21 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:71335-1503-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:71335-1503-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
4	NDC:71335-1503-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
5	NDC:71335-1503-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
6	NDC:71335-1503-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
7	NDC:71335-1503-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
8	NDC:71335-1503-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
9	NDC:71335-1503-8	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
10	NDC:71335-1503-9	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71335-1517(NDC:49483-602)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	400 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1517-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
2	NDC:71335-1517-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
3	NDC:71335-1517-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
4	NDC:71335-1517-4	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
5	NDC:71335-1517-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
6	NDC:71335-1517-6	120 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
7	NDC:71335-1517-7	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
8	NDC:71335-1517-8	21 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
9	NDC:71335-1517-9	15 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1517, 71335-1396, 71335-1503) , RELABEL(71335-1396, 71335-1503, 71335-1517)