IBUPROFEN- ibuprofen tablet, film coated
TIME CAP LABORATORIES, INC

IBUPROFEN 400 MG - 600 MG AND 800 MG TABLETS

ibuprofen tablets 400 mg - 600 mg- 800 mg medguide

HOW SUPPLIED

400mg (white to of white, round, biconvex, film coated tablets debossed with '121' on one side and plain on the other side) Bottles of 100 & 500

HOW SUPPLIED

600mg (white to off white, capsule shaped, biconvex, film coated tablets debossed with '122' on one side and plain on the other side) Bottles of 30, 50, 100 & 500

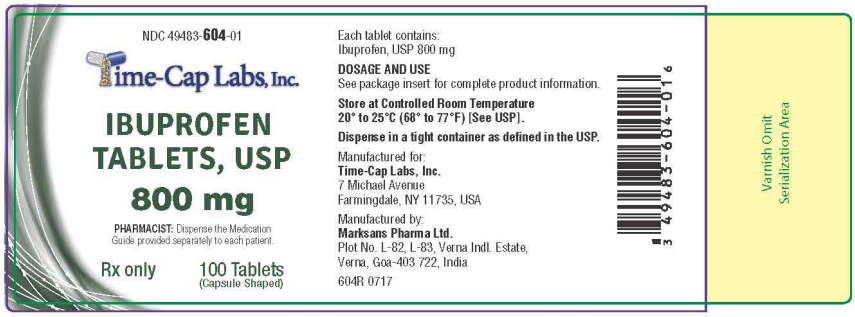
800 mg (white to off-white, capsule shaped, biconvex, film-coated tablets debossed with ‘123’ on one side and plain on other side)

400mg Ibuprofen 100 count label

400 mg 500 count label

600 mg 100 count label

800 mg 100 count label



600 MG 500 COUNT LABEL

800 MG 500 COUNT LABEL

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED 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:49483-602-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-602-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

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: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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED 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:49483-603-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-603-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
3	NDC:49483-603-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
4	NDC:49483-603-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

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: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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED 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:49483-604-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-604-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
3	NDC:49483-604-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
4	NDC:49483-604-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information

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

Labeler - TIME CAP LABORATORIES, INC (037052099)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-602, 49483-603, 49483-604)

Revised: 12/2019 TIME CAP LABORATORIES, INC