

IBUPROFEN- ibuprofen tablet, film coated
PD-Rx Pharmaceuticals, Inc.

IBUPROFEN 800 MG TABLETS

ibuprofen tablets 400 mg - 600 mg- 800 mg medguide

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

Bottles of 4, 6, 9, 10, 12, 15, 18, 20, 21, 24, 28, 30, 40, 60, 90, 100, 180, 270 and 500.

800 mg label

ALCOHOL OR ALCOHOLIC BEVERAGES SHOULD NOT BE CONSUMED WHILE TAKING THIS MEDICATION.

R only WARNING: KEEP THIS OUT OF THE REACH OF CHILDREN
 DOSAGE and STORAGE: SEE PACKAGE INSERT

43063-858-15	43063-858-15	43063-858-15
IBUPROFEN USP	IBUPROFEN USP	IBUPROFEN USP
800 MG	800 MG	800 MG
15 TABLETS	15 TABLETS	15 TABLETS
ReOrder # 110555	ReOrder # 110555	ReOrder # 110555
LOT H19E39	LOT H19E39	LOT H19E39
EXP 11/2020	EXP 11/2020	EXP 11/2020

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS.
 YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088

TAKE _____ TABLET(S) _____ TIMES A DAY WITH FOOD.
 TOME _____ TABLETA(S) _____ VECES AL DIA CON COMIDA.

Each TABLET Contains: IBUPROFEN USP 800 MG



NDC: 43063-858-15



IBUPROFEN USP

800 MG
15 TABLETS



GTIN: 00343063858158
 SNO: H19E39000003
 EXP: 11/2020
 LOT: H19E39

343063858158
 49483060450
 MARKSANS PHARMA, LTD.
 VERNIA GOA, 403 722 INDIA

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43063-858(NDC:49483-604)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	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:43063-858-04	4 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/22/2018	
2	NDC:43063-858-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2019	
3	NDC:43063-858-09	9 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2019	
4	NDC:43063-858-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/06/2018	
5	NDC:43063-858-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
6	NDC:43063-858-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
7	NDC:43063-858-18	18 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
8	NDC:43063-858-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/21/2018	
9	NDC:43063-858-21	21 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2018	
10	NDC:43063-858-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2019	
11	NDC:43063-858-28	28 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/24/2019	
12	NDC:43063-858-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
13	NDC:43063-858-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/03/2018	
14	NDC:43063-858-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
15	NDC:43063-858-82	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2020	
16	NDC:43063-858-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
17	NDC:43063-858-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2019	
18	NDC:43063-858-93	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	
19	NDC:43063-858-94	270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2018	

Marketing Information

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

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(43063-858)

Revised: 3/2020

PD-Rx Pharmaceuticals, Inc.