

**IBUPROFEN- ibuprofen tablet, film coated**  
**Aphena Pharma Solutions - Tennessee, LLC**

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**IBUPROFEN 400 MG - 600 MG AND 800 MG TABLETS**

**ibuprofen tablets 400 mg - 600 mg- 800 mg medguide**

**HOW SUPPLIED**

400mg (white to off 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

**HOW SUPPLIED**

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

**Repackaging Information**

Please reference the *How Supplied* section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

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<b>Count</b>	<b>800 mg</b>
90	71610-387-60

180 71610-387-80  
 270 71610-387-92

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

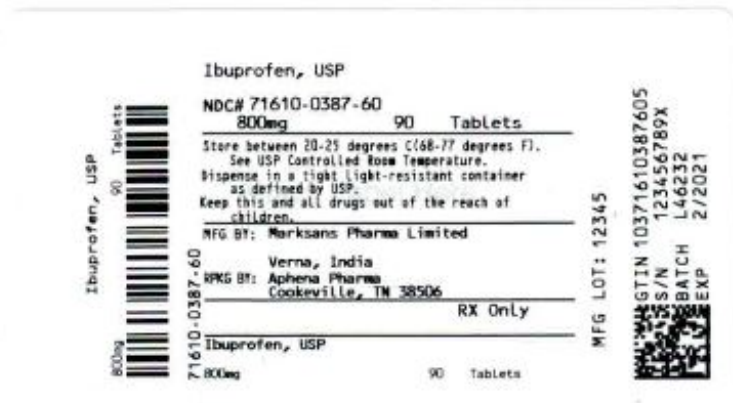


Cookeville, TN 38506

20200122JH

**PRINCIPAL DISPLAY PANEL - 800 mg**

NDC 71610-387 - Ibuprofen, USP 800 mg Tablets - Rx Only



**IBUPROFEN**

ibuprofen tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71610-387(NDC:49483-604)
<b>Route of Administration</b>	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)	
CROSCARMELOSE 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:71610-387-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2020	
2	NDC:71610-387-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2020	
3	NDC:71610-387-92	270 in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2020	

### Marketing Information

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

**Labeler** - Aphena Pharma Solutions - Tennessee, LLC (128385585)

### Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-387)

Revised: 1/2020

Aphena Pharma Solutions - Tennessee, LLC