IBUPROFEN- ibuprofen tablet, film coated
AiPing Pharmaceutical, Inc.

IBUPROFEN CAPLETS, USP 200mg

Important

Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- temporarily reduces fever

Warnings

Allergy alert

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning:

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Brown Film-Coated Caplets contain FD+C Yellow No. 5 (tartrazine) as a color additive

Do not use
- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if
- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product
- take with food or milk if stomach upset occurs

Stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor

because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**

adults and children 12 years and older

- take 1 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years

- ask a doctor

Orange, Capsule-shaped Tablet, debossed with BI 03

Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow #10, FD&C Blue #2, FD&C Yellow #6, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

White, Capsule-shaped Tablet, debossed with BI 05

Colloidal Silicon Dioxide, Croscarmellose Sodium, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

Brown, Capsule-shaped Tablet, debossed with BI 07

Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide Red, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

Questions or comments?

Call **1-844-374-0016** Monday through Friday 9AM - 5PM EST.

WARNING:

KEEP OUT OF THE REACH OF CHILDREN. THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.

Orange, Capsule-shaped Tablet, debossed with BI 03

Quantity : 50864 Tablets
NDC No.: 11788-003-00

AiPing PHARMACEUTICAL, INC.

Ibuprofen Tablets, USP 200 mg (Orange, Capsule Shaped)
布洛芬片，USP 200 mg （橙色，胶囊形）

STRENGTH:	Each Tablet Contains 每片含:
规格	Ibuprofen 200 mg 布洛芬 200 mg
NDC:	11788-003-00

QUANTITY:	50,864 Tablets	**NET WT.:**	15 Kg/Case
数量	50,864 片	**净重**	15 公斤/箱
LOT:			
批号			
MFG. DATE:		**PKG. BY DATE:**	
生产日期		**最终包装有效期**	
STORAGE:	Store at room temperature 15-30°C		
储藏	室温 15-30°C 下保存		
MANUFACTURER:	Anshi Pharmaceutical (Zhongshan) Inc.		
生产企业	National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地		
FOR:	AiPing Pharmaceutical, Inc.		
委托方	Hauppauge, NY 11788 USA		

AiPing PHARMACEUTICAL, INC.

SHIPPING LABEL

PRODUCT NAME:	**Ibuprofen Tablets, USP 200 mg (Orange, Capsule Shaped)**
产品名称	**布洛芬片，USP 200 mg （橙色，胶囊形）**
GROSS WEIGHT:	16 Kg/Case
毛重	16 公斤/箱
VOLUME:	0.33 M× 0.3 M× 0.3 M= 0.030 M^3
体积	0.33 米×0.3 米×0.3 米= 0.030 立方米
SHIP TO:	AiPing Pharmaceutical, Inc.
运往	Hauppauge, NY 11788 USA
TELEPHONE:	1-844-374-0016
电话	

WARNING:	**KEEP OUT OF THE REACH OF CHILDREN**
敬告	**请存放在儿童不能接触的地方**
	THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.
	该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

White, Capsule-shaped Tablet, debossed with BI 05

Quantity : 50864 Tablets
NDC No.: 11788-005-00

Ibuprofen Tablets, USP 200 mg (White, Capsule Shaped)
布洛芬片，USP 200 mg （白色，胶囊形）

STRENGTH: **规格**	Each Tablet Contains 每片含: Ibuprofen 200 mg 布洛芬 200 mg		
NDC:	11788-005-00		
QUANTITY: **数量**	50,864 Tablets 50,864 片	**NET WT.:** **净重**	15 Kg/Case 15 公斤/箱
LOT: **批号**			
MFG. DATE: **生产日期**		**PKG. BY DATE:** **最终包装有效期**	
STORAGE: **储藏**	Store at room temperature 15-30°C 室温 15-30°C 下保存		
MANUFACTURER: 生产企业	Anshi Pharmaceutical (Zhongshan) Inc. National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地		
FOR: 委托方	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA		

SHIPPING LABEL

PRODUCT NAME: 产品名称	**Ibuprofen Tablets, USP 200 mg (White, Capsule Shaped)** **布洛芬片，USP 200 mg （白色，胶囊形）**
GROSS WEIGHT: 毛重	16 Kg/Case 16 公斤/箱
VOLUME: 体积	0.33 M× 0.3 M× 0.3 M= 0.030 M^3 0.33 米×0.3 米×0.3 米= 0.030 立方米
SHIP TO: 运往	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA
TELEPHONE: 电话	1-844-374-0016
WARNING: 敬告	**KEEP OUT OF THE REACH OF CHILDREN** **请存放在儿童不能接触的地方** **THIS IS A BULK SHIPMENT INTENDED FOR FURTHER**

PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.
该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

Brown, Capsule-shaped Tablet, debossed with BI 07

Quantity : 50864 Tablets
NDC No.: 11788-007-00

AiPing PHARMACEUTICAL, INC.

Ibuprofen Tablets, USP 200 mg (Brown, Capsule Shaped)
布洛芬片，USP 200 mg （棕色，胶囊形）

STRENGTH:	Each Tablet Contains 每片含:		
规格	Ibuprofen 200 mg 布洛芬 200 mg		
NDC:	11788-007-00		
QUANTITY:	50,864 Tablets	**NET WT.:**	15 Kg/Case
数量	50,864 片	**净重**	15 公斤/箱
LOT:			
批号			
MFG. DATE:		**PKG. BY DATE:**	
生产日期		**最终包装有效期**	
STORAGE:	Store at room temperature 15-30°C		
储藏	室温 15-30°C 下保存		
MANUFACTURER:	Anshi Pharmaceutical (Zhongshan) Inc.		
生产企业	National Health Technology Park, Zhongshan, Guangdong, P.R. China 安士制药（中山）有限公司 中国广东省中山市国家健康科技产业基地		
FOR:	AiPing Pharmaceutical, Inc.		
委托方	Hauppauge, NY 11788 USA		

AiPing PHARMACEUTICAL, INC.

SHIPPING LABEL

PRODUCT NAME:	**Ibuprofen Tablets, USP 200 mg (Brown, Capsule Shaped)**
产品名称	**布洛芬片，USP 200 mg （棕色，胶囊形）**
GROSS WEIGHT:	16 Kg/Case
毛重	16 公斤/箱
VOLUME:	0.33 M× 0.3 M× 0.3 M= 0.030 M^3

体积	0.33 米×0.3 米×0.3 米= 0.030 立方米
SHIP TO: 运往	AiPing Pharmaceutical, Inc. Hauppauge, NY 11788 USA
TELEPHONE: 电话	1-844-374-0016

WARNING: 敬告	**KEEP OUT OF THE REACH OF CHILDREN** 请存放在儿童不能接触的地方 **THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE REPACKAGED IMMEDIATELY AND LABELED IN STRICK CONFORMANCE WITH THE FOOD DRUG & COSMETIC ACT AND REGULATIONS THEREUNDER.** 该产品散装，应尽快进行再包装并贴有完全符合食品、药品和化妆品管理法案及其他法规要求的标示。

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11788-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	15mm
Flavor		**Imprint Code**	BI;03
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11788-003-00	50864 in 1 CARTON; Type 0: Not a Combination Product	05/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	05/08/2017	

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11788-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
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**	15mm
Flavor		**Imprint Code**	BI;05
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11788-005-00	50864 in 1 CARTON; Type 0: Not a Combination Product	05/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	05/08/2017	

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11788-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	CAPSULE	**Size**	15mm
Flavor		**Imprint Code**	BI;07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11788-007-00	50864 in 1 CARTON; Type 0: Not a Combination Product	05/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	05/08/2017	

Labeler - AiPing Pharmaceutical, Inc. (079674526)

Registrant - AiPing Pharmaceutical, Inc. (079674526)

Establishment

Name	Address	ID/FEI	Business Operations
Anshi Pharmaceutical (Zhongshan) Inc.		528101821	manufacture(11788-003, 11788-005, 11788-007)

Revised: 9/2017 AiPing Pharmaceutical, Inc.