

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

Ibuprofen Caplets, USP 200 mg

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

Other information

- store between 20-25°C (68-77°F)
- **do not use if the inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing**

Questions or comments?

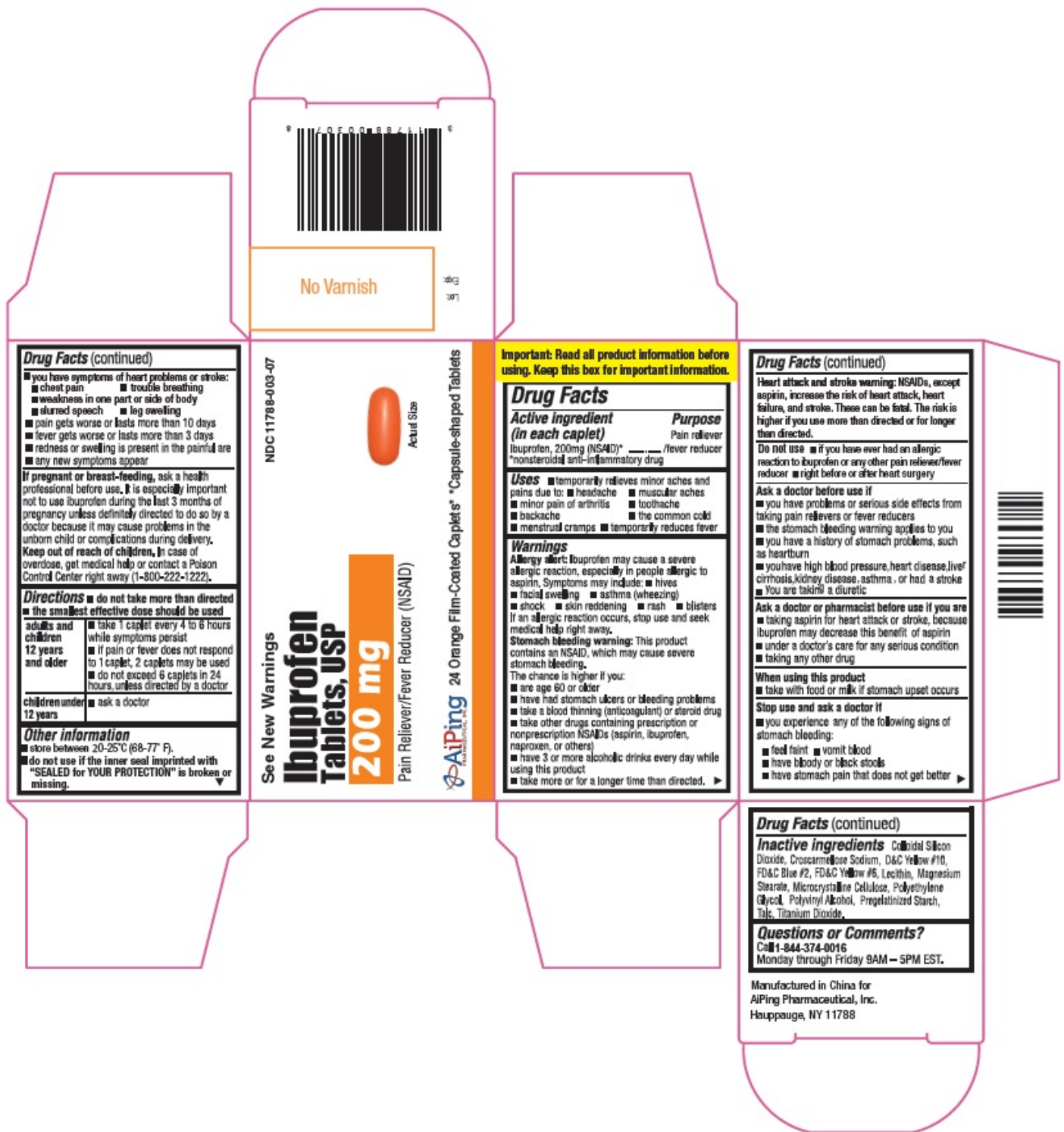
Call **1-844-374-0016** Monday through Friday 9AM - 5PM EST.

Ibuprofen tablets are available in the following colors and sizes:

Orange, Capsule-shaped Tablet, debossed with BI 03

Bottles of 24 NDC 11788-003-07


Bottles of 1000 NDC 11788-003-10



White, Capsule-shaped Tablet, debossed with BI 05

Bottles of 24 NDC 11788-005-07

Bottles of 1000 NDC 11788-005-10



No Varnish

Drug Facts (continued)


- 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

| | |
|---|--|
| <ul style="list-style-type: none"> ■ do not take more than directed ■ the smallest effective dose should be used <p>adults and children 12 years and older</p> <ul style="list-style-type: none"> ■ 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 <p>children under 12 years</p> <ul style="list-style-type: none"> ■ ask a doctor | <p>Other information</p> <ul style="list-style-type: none"> ■ store between 20-25°C (68-77°F). ■ do not use if the inner seal imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing. |
|---|--|

NDC 11788-005-07



Actual Size

24 White Film-Coated Caplets*

See New Warnings

Ibuprofen Tablets, USP

200 mg

Pain Reliever/Fever Reducer (NSAID)

AiPing Pharmaceutical, Inc.

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

Drug Facts

| | |
|---|---|
| <p>Active ingredient (in each caplet)</p> <p>Ibuprofen, 200mg (NSAID)*</p> <p>*nonsteroidal anti-inflammatory drug</p> | <p>Purpose</p> <p>Pain reliever</p> <p>fever reducer</p> |
|---|---|

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:

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- have 3 or more alcoholic drinks every day while using this product

take more or for a longer time than directed. ▶

Drug Facts (continued)

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.

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

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- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
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- under a doctor's care for any serious condition
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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

Drug Facts (continued)

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

Questions or Comments?

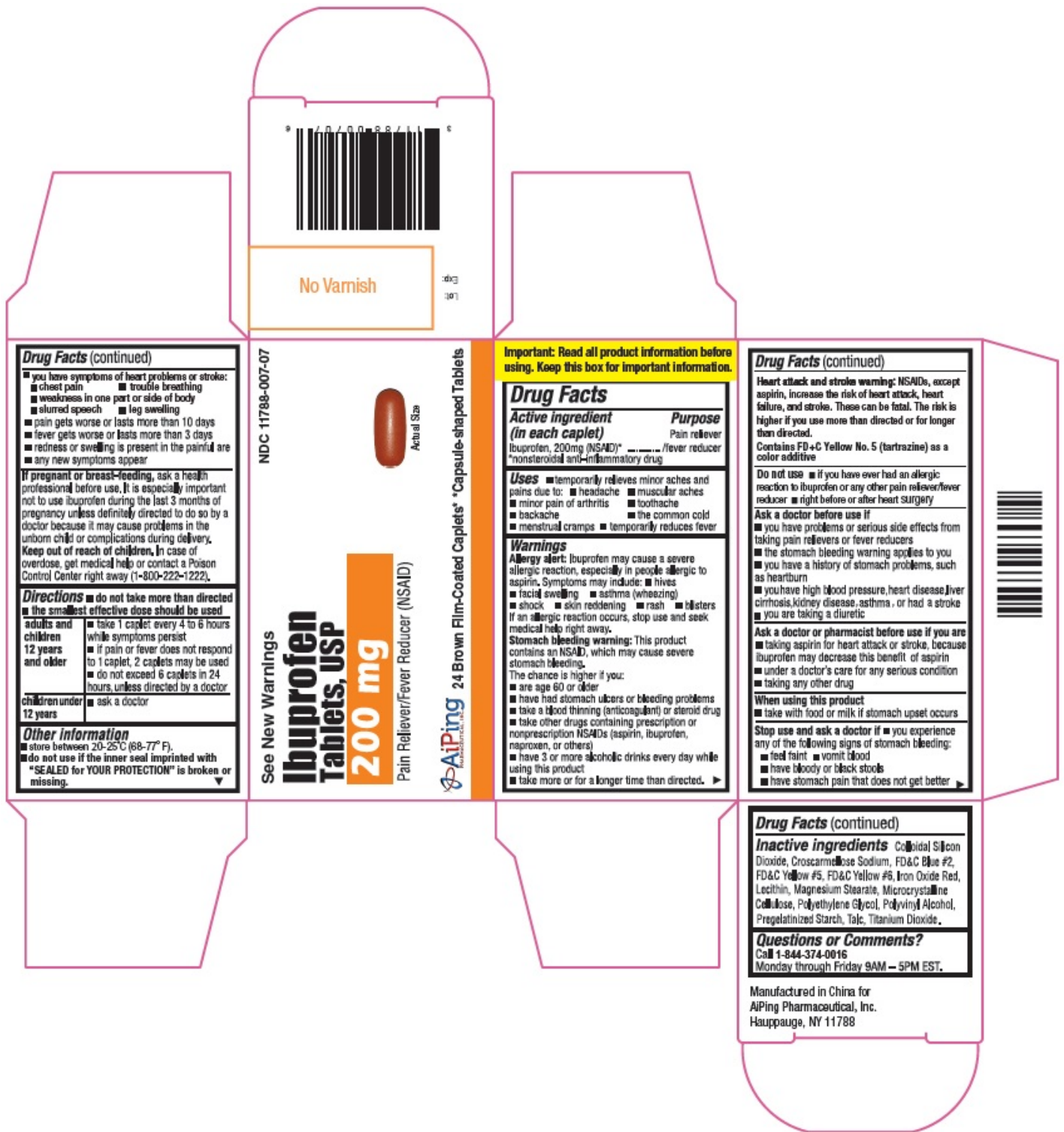
Call 1-844-374-0016
Monday through Friday 9AM – 5PM EST.

Manufactured in China for
AiPing Pharmaceutical, Inc.
Hauppauge, NY 11788

Brown, Capsule-shaped Tablet, debossed with BI 07

Bottles of 24 NDC 11788-007-07

Bottles of 1000 NDC 11788-007-10



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) | |
| CROSCARMELOSE 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: 4R4HF16D95) | |
| 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:11788-003-07 | 1 in 1 CARTON | 05/08/2017 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:11788-003-10 | 1000 in 1 BOTTLE; 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) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95) | |
| 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:11788-005-07 | 1 in 1 CARTON | 05/08/2017 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:11788-005-10 | 1000 in 1 BOTTLE; 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) | |
| CROSCARMELOSE 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: 4R4HF16D95) | |
| 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:11788-007-07 | 1 in 1 CARTON | 05/08/2017 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:11788-007-10 | 1000 in 1 BOTTLE; 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. | | 528 10 18 21 | manufacture(11788-003, 11788-005, 11788-007) |

Revised: 10/2017

AiPing Pharmaceutical, Inc.