

**IBUPROFEN SOFTGELS- ibuprofen capsule**  
**Breeden Brothers, LLC**

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**Ibuprofen Softgels**

***Drug Facts***

***Active ingredient (in each capsule)***

Solubilized ibuprofen equal to Pain reliever/ 200 mg ibuprofen (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***Purpose***

fever reducer (present as the free acid and potassium salt)

***Drug Facts*** (continued)

***Uses***

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

***Warnings***

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

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

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:

take a blood thinning (anticoagulant) or

**Drug Facts** (continued)

steroid drug

are age 60 or older

have had stomach ulcers or bleeding problems

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

**Do not use**

if you have ever had an allergic reaction to any other pain reliever/fever reducer

right before or after heart surgery

**Ask a doctor before use if**

stomach bleeding warning applies to you

you have a history of stomach problems, such as heartburn

you are taking a diuretic

**Drug Facts** (continued)

you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma

you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**

taking any other drug

under a doctor's care for any serious condition

taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin

**When using this product**

take with food or milk if stomach upset occurs

the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

**Stop use and ask a doctor if**

you experience any of the following signs of

**Drug Facts** (continued)

stomach bleeding:

feel faint

have stomach pain that does not get better

have bloody or black stools

vomit blood

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)

**Drug Facts** (continued)

**Directions**

- \_ **do not take more than directed**
- \_ **the smallest effective dose should be used**
- \_ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- \_ if pain or fever does not respond to 1 capsule, 2 capsules may be used
- \_ do not exceed 6 capsules in 24 hours, unless directed by a doctor
- \_ children under 12 years: ask a doctor

**Other information**

- \_ **each capsule contains:** potassium 28 mg
- \_ read all warnings and directions before use.
- \_ store at 20°-25°C (68°-77°F)
- \_ avoid excessive heat above 40°C (104°F)

**Drug Facts** (continued)

**Inactive ingredients**

FD&C green #3, gelatin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol special, and white edible ink

**Questions or comments?**

**1-800-901-2420**

Product of China

**PRINCIPAL DISPLAY PANEL**

b+b  
better by giving  
IBUPROFEN  
SOFTGELS

20 Softgels  
(200 mg each)



**PRINCIPAL DISPLAY PANEL**

b+b  
better by giving  
IBUPROFEN  
SOFTGELS  
40 Softgels  
(200 mg each)



**PRINCIPAL DISPLAY PANEL**

NDC 70729-509-32

b+b

IBUPROFEN

SOFTGELS

120 Softgels

(200 mg each)



# IBUPROFEN SOFTGELS

Ibuprofen Tablets USP, 200 mg  
Pain Reliever/Fever Reducer  
(NSAID)



120 Softgels



NDC 70729-509-32

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAPS BROKEN OR MISSING

### Drug Facts

#### Active Ingredient (in each capsule)

Substituted Ibuprofen equal to 200 mg (Ibuprofen (NSAID)\* ..... Pain reliever/fever reducer (present as the free acid and potassium salt) \*nonsteroidal anti-inflammatory drug

#### Uses

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

#### Warnings

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

- facial swelling
- shock
- asthma (wheezing)
- skin reddening
- hives
- 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.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if

- you are taking a diuretic
- you have a history of stomach problems, such as heartburn

70729-0RG021850832

Dist. by Breedem Brothers, LLC Nashville, TN 37206

PEEL HERE FOR MORE DRUG FACTS

## IBUPROFEN SOFTGELS

ibuprofen capsule

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:70729-000 |
| Route of Administration | ORAL           |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN         | 200 mg   |

### Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)           |          |
| GELATIN (UNII: 2G86QN327L)                    |          |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)          |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)       |          |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)        |          |
| WATER (UNII: 059QF0K00R)                      |          |
| SORBITOL (UNII: 506T60A25R)                   |          |

### Product Characteristics

|          |         |              |          |
|----------|---------|--------------|----------|
| Color    | GREEN   | Score        | no score |
| Shape    | CAPSULE | Size         | 18 mm    |
| Flavor   |         | Imprint Code |          |
| Contains |         |              |          |

### Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code        | Package Description  | Date       | Date |
|---|------------------|--|------------|------|
| 1 | NDC:70729-000-01 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/01/2018 |      |
| 2 | NDC:70729-000-02 | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/01/2018 |      |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA206568                               | 02/01/2018           |                    |

## IBUPROFEN SOFTGELS

ibuprofen capsule

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:70729-509 |
| Route of Administration | ORAL           |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN         | 200 mg   |

### Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)           |          |
| GELATIN (UNII: 2G86QN327L)                    |          |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)          |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)       |          |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)        |          |
| WATER (UNII: 059QF0KO0R)                      |          |
| SORBITOL (UNII: 506T60A25R)                   |          |

### Product Characteristics

|          |         |              |          |
|----------|---------|--------------|----------|
| Color    | GREEN   | Score        | no score |
| Shape    | CAPSULE | Size         | 18mm     |
| Flavor   |         | Imprint Code |          |
| Contains |         |              |          |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

|   |                  |   |            |  |
|---|------------------|---|------------|--|
| 1 | NDC:70729-509-32 | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/01/2018 |  |
|---|------------------|---|------------|--|

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA206568                               | 02/01/2018           |                    |

**Labeler** - Breeden Brothers, LLC (080131046)

Revised: 1/2018

Breeden Brothers, LLC