#### IBUPROFEN- ibuprofen tablet, film coated H E B

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# HEB Ibuprofen Tablets 200 mg Drug Facts

## Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

## Purposes

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.

## 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 at 20 weeks or later in 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

- read all warnings and directions before use
- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- see end panel for lot number and expiration date

## Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

## **Questions or comments?**

1-800-719-9260

## **Principal Display Panel**

Compare to Motrin<sup>®</sup> IB Ibuprofen Caplets active ingredient

See Revised Warning

#### $\text{H-E-B}_{\mathbb{R}}$

Ibuprofen Tablets USP, 200 mg

Pain Reliever / Fever Reducer (NSAID)

For Body Aches and Pains

actual size

50 COATED CAPLETS\*\*

\*\*Capsule-Shaped Tablets



| Product Information                       |          |               |
|---|----------|---------------|
| Product Type HUMAN OTC DRUG Item Code (So | ource) N | IDC:37808-709 |
| Route of Administration ORAL              |          |               |

| Ingredient Name     Basis of Strength     Strength       IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)     IBUPROFEN     200 mg       Inactive Ingredients     Ingredient Name     Strength       STARCH, CORN (UNII: ET7/26XBU4)     Strength     Strength       STARCH, CORN (UNII: B232XY35))     Strength     Strength       FD&C RED NO. 40 (UNII: WZ89127XOA)     FD     Strength       FD&C RED NO. 40 (UNII: WZ89127XOA)     Strength     Strength       FD&C RED (UNII: H77YEIB3A8)     Strength     Strength       FD&C VELLOW NO. 6 (UNII: H77YEIB32061U)     Strength     Strength       POLYINYL ALCOHOL, UNSPECIFIED (UNII: S32859990)     Strength     Strength       TALC (UNII: 75EV7J4R1U)     Strength     Strength     Strength       TALC (UNII: 75EV7J4R1U)     Strength     Strength     Strength       TALC (UNII: S15FK9V2JP)     Strength     I     Strength     Strength       Strength     OVAL     Size     14mm     Strength       Strength     I     Ingredi  |                                 |                             |                  |            |                       |  |
|---|---------------------------------|-----------------------------|------------------|------------|-----------------------|--|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) IBUPROFEN 200 mg  Inactive Ingredients Ingredient Name Strength SILICON DIOXIDE (UNII: ET/T26XBU4) STARCH, CORN (UNII: 08232NY35)) CROSCARRELOSE SODUM (UNII: M280L1H48) FD&C RED NO. 40 (UNII: WZ89127XOA) FD&C YELLOW NO. 6 (UNII: H77VE1938) FD&C YELLOW NO. 6 (UNII: H77VE1938) FERRIC OXIDE RED (UNII: H77VE19348) FERRIC OXIDE RED (UNII: H77VE19348) FERRIC OXIDE RED (UNII: H77VE19348) FERRIC OXIDE RED (UNII: 15FK9V2) FTARL ACID (UNII: 15FK9V2) FTALL ACID (UNII: 1   | Active Ingredient/Active Moiety |                             |                  |            | anath Steanath        |  |
| Ingredients         Strength         Strength     <   | -                               |                             |                  |            |                       |  |
| Ingredient Name       Strength         SILCON DIOXIDE (UNII: ETJ7Z 6X8U4)         STARCH, CORM (UNII: 0232NY35))         CROSCARMELLOSE SOLUMU (UNII: W28011HH48)         FD&C RED NO. 40 (UNII: W28012HH48)         FD&C RED NO. 40 (UNII: H77VEI93A8)         FERRIC OXIDE RED (UNII: 1K09736675)         MICROCRYSTALING CELUILOSE (UNII: 091R32D61U)         POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 30400SDW1A)         POLYETHYLENE GLYCZ JARDY         STEARIC ACID (UNII: 1SFIN9V2JP)         INFORMET Characteristics         Colspan= OVAL         Size         NOVAL         Size         Imprint Code         Imprint Code         Polycolspan="2">Imprint Code         Size         Polycolspan= Size         Imprint Code         Imprint Code         Imprint Code         Imprint Code         Impro   |                                 |                             |                  | IDDITIONEN | 200 mg                |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)<br>STARCH, CORN (UNII: 08232NY35))<br>CROSCARMELLOSE SODIUM (UNII: M280L1HH48)<br>FD6C RED NO. 6 (UNII: H77VE193A8)<br>FD6C RED NO. 6 (UNII: H77VE193A8)<br>FERRIC OXIDE RED (UNII: 1K09F3G675)<br>MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U)<br>POLYTIMYL ALCOHOL, UNSPECIFIED (UNII: 33285)990)<br>STEARIC ACID (UNII: 4ELV7Z65AP)<br>TALC (UNII: 7SEV7JAR1U)<br>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)<br>Product Characteristics<br>Color ORANGE Score no score<br>Shape OVAL Size Idams Ida   | Inactive Ingre                  | dients                      |                  |            |                       |  |
| STARCH, CORN (UNII: 08232NY35)) <td< td=""><td></td><td>Ingred</td><td>lient Name</td><td></td><td>Strength</td></td<>  |                                 | Ingred                      | lient Name       |            | Strength              |  |
| CROSCARMELLOSE SODIUM (UNII: M2B011HH48)  |                                 | (UNII: ETJ7Z6XBU4)          |                  |            |                       |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA)       Image: Constant of the second se   | STARCH, CORN (UI                | NII: 08232NY3SJ)            |                  |            |                       |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)  | CROSCARMELLOS                   | E SODIUM (UNII: M280L1H     | IH48)            |            |                       |  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)       Image: Content of the state of the stat   | FD&C RED NO. 40                 | (UNII: WZ B9127XOA)         |                  |            |                       |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)<br>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 33WQ0SDW1A)<br>POLYINYL ALCOHOL, UNSPECIFIED (UNII: 332859)990)<br>STEARIC ACID (UNII: 4LV7265AP)<br>TALC (UNII: 75EV7]4R1U)<br>TTALC (UNII: 75EV7]4R1U)<br>TTALC (UNII: 75EV7]4R1U)<br>POLUCT Characteristics<br>Color V 0RANGE Score no score<br>Shape 0VAL Size 14mm<br>Flavor 0VAL Size 14mm<br>Flavor 102 12<br>Contains 12<br>POLS 14 10 ARTON 08/21/2006 12<br>Marketing End Date<br>1 in 1 CARTON 08/21/2006 12<br>1 in 1 CARTON 08/21/2006 12<br>Marketing End Date<br>Marketing Start Marketing End Date<br>Marketing Start Marketing End Date<br>Marketing Start Marketing End Date<br>Marketing Information  | FD&C YELLOW NO                  | . 6 (UNII: H77VEI93A8)      |                  |            |                       |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQOSDWLA)<br>POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>TALC (UNII: 75EV7J4R1U)<br>TTANIUM DIOXIDE (UNII: 15FIX9V2JP)<br>TTANIUM DIOXIDE (UNII: 15FIX9V2JP)<br>POduct Characteristics<br>Color ORANGE Score no score<br>Shape OVAL Size 14mm<br>Flavor OVAL Size 14mm<br>Flavor 0VAL 006 12<br>Flavor 0VAL 006 12<br>Flavor 008/21/2006 12<br>Marketing Start 008/2008 12<br>Marketing Start 008/2008 12  | FERRIC OXIDE RED                | <b>)</b> (UNII: 1K09F3G675) |                  |            |                       |  |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532859)990)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>TALC (UNII: 7SEV7J4R1U)<br>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)<br>Product Characteristics<br>Color ORANGE Score no score<br>Shape OVAL Size 14mm<br>Flavor 0VAL Size 14mm<br>Flavor 0VAL Size 2000 14mm<br>Flavor 0VAL 000 14mm<br>Flavor 000 14mm<br>Fl | MICROCRYSTALLIN                 | NE CELLULOSE (UNII: OP1     | R32D61U)         |            |                       |  |
| STEARIC ACID (UNII: 4ELV7265AP)       Image: Stearic Acid (UNII: 75EV7)4R1U)         TALC (UNII: 75EV7)4R1U)       Image: Stearic Acid (UNII: 15FIX9V2)P)         Product Characteristics       Image: Stearic Acid (UNII: 15FIX9V2)P)         Product Product       Image: Stearic Acid (UNII: 15FIX9V2)P)         Product Product Product       Image: Stearic Acid (UNII: 15FIX9V2)P)         Product Product Product Product Produc  | POLYETHYLENE G                  | LYCOL, UNSPECIFIED (UN      | NII: 3WJQ0SDW1A) |            |                       |  |
| TALC (UNII: 75EV7J4R1U)<br>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics  Product Characteristics  V ORANGE OVAL Size I4mm Imprint Code I2 Contains  V V V V V V V V V V V V V V V V V V   | POLYVINYL ALCOH                 | IOL, UNSPECIFIED (UNII:     | 532B59J990)      |            |                       |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics  Color ORANGE Score no score Shape OVAL Size 14mm  Flavor Unit: 15FIX9V2JP  Flavor Inprint Code Inprint Code 12  Contains Inprint Code 12  Packaging  Marketing Start Date Marketing End Date  Marketing InprintCode Information  Marketing Lifermation  Marketing Application Number or Monograph Marketing Start Date Information  Marketing Category Application Number or Monograph Marketing Start Date Information  Output  Description Information  Output  Description Information  Product  Output  Description  Output   | STEARIC ACID (UNI               | II: 4ELV7Z65AP)             |                  |            |                       |  |
| Product Characteristics         Color       ORANGE       Score       no score         Shape       OVAL       Size       14mm         OVAL       Size       14mm         Flavor       Imprint Code       12         Contains       Packaging       Marketing Start       Marketing End Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC: 37808-709-<br>1       1 in 1 CARTON       08/21/2006       1       1       1       Other Comparison       Marketing End Date         Marketing Information         Marketing Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date  | TALC (UNII: 7SEV7J4             | IR1U)                       |                  |            |                       |  |
| Color       ORANGE       Score       no score         Sh→pe       OVAL       Size       14mm         Flavor       Imprint Code       Imprint Code       12         Flavor       Imprint Code       Marketing Start       Marketing End Date         NDC:37808-709-<br>1       1 in 1 CARTON       08/21/2006       Marketing Start       Marketing End Date         More the interval of the in   | TITANIUM DIOXIDE                | (UNII: 15FIX9V2JP)          |                  |            |                       |  |
| Color       ORANGE       Score       no score         Sh→pe       OVAL       Size       14mm         Flavor       Imprint Code       Imprint Code       Iz         Contains       State       Marketing Start       Marketing End Date         Marketing Code       So in 1 BOTTLE; Type 0: Not a Combination Product       08/21/2006       Imprint Code         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Start Date   | Product Chara                   | acteristics                 |                  |            |                       |  |
| Shape       OVAL       Size       14mm         Flavor       Size       Imprint Code       Iz         Imprint Code       Package       Marketing Start       Marketing End Date         M       NDC: 37808-709-<br>71       1 in 1 CARTON       08/21/2006       Marketing Start         M       Dot       So in 1 BOTTLE; Type 0: Not a Combination<br>Product       So in 1 BOTTLE; Type 0: Not a Combination       Marketing Start       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start       Marketing End Date  |                                 |                             |                  |            |                       |  |
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| #       Item Code       Package Description       Marketing Start<br>Date       Marketing End<br>Date         1       NDC:37808-709-<br>71       1 in 1 CARTON       08/21/2006       Image: Comparison of the start         1       50 in 1 BOTTLE; Type 0: Not a Combination<br>Product       50 in 1 BOTTLE; Type 0: Not a Combination       Image: Comparison of the start       Image: Comparison of the start         Marketing Tromation         Marketing Start Date         Marketing Category       Application Number or Monograph<br>Citation       Marketing Start       Marketing End<br>Date   | contains                        |                             |                  |            |                       |  |
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| ANDA ANDA077349 07/04/2006  |                                 |                             |                  |            | Marketing End<br>Date |  |
|   | ANDA                            | ANDA077349                  |                  | 07/04/2006 |                       |  |

Labeler - H E B (007924756)