

FOSTER AND THRIVE IBUPROFEN- ibuprofen tablet, film coated
Strategic Sourcing Services LLC

McKesson Ibuprofen 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, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

Questions or comments?

Call **833-358-6431** Monday to Friday 9:00am to 7:00pm EST

Principal Display Panel

COMPARE TO ADVIL® ACTIVE INGREDIENT

Foster & Thrive™

Ibuprofen Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

Gluten Free

ACTUAL SIZE

SEE REVISED WARNING

50 COATED CAPLETS**

**Capsule-Shaped Tablets


Drug Facts

Active ingredient
(in each caplet)
ibuprofen 200 mg (NSAID)* Pain reliever/fever reducer
nonsteroidal anti-inflammatory drug

Purposes

Uses ■ temporarily relieves minor aches and pains due to:
 ■ headache ■ muscle 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)
 ■ itches ■ skin redness ■ rash ■ blisters
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 ■ 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



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 ■ 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
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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 3 days
 ■ redness or swelling is present in the painful area ■ any new symptoms appear

Drug Facts (continued)

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

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 ■ avoid high humidity and excessive heat above 40°C (104°F)
 ■ see and panel for lot number and expiration date

Inactive ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide



NDC 70677-1136-1

Foster & Thrive™

Ibuprofen

Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

Gluten Free

SEE REVISED WARNING

COMPARE TO ADVIL®
ACTIVE INGREDIENT***



ACTUAL SIZE

50 COATED CAPLETS**

**Capsule-Shaped Tablets




FOSTER AND THRIVE IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70677-1136

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) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | | | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | BROWN | Score | no score | |
| Shape | OVAL | Size | 15mm | |
| Flavor | | Imprint Code | I2 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70677-1136-1 | 1 in 1 CARTON | 10/20/2023 | |
| 1 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:70677-1136-2 | 1 in 1 CARTON | 10/20/2023 | |
| 2 | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:70677-1136-3 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 10/20/2023 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| ANDA | ANDA072096 | | 10/20/2023 | |

Labeler - Strategic Sourcing Services LLC (116956644)

