7 SELECT IBUPROFEN- ibuprofen tablet, film coated 7-Eleven

7-Eleven Ibuprofen Tablets, 200 mg Drug Facts

Active ingredient (in each tablet)

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 chances are 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

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

- 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, or kidney disease
- you have asthma
- 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
- 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 stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- 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 tablet every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 tablet, 2 tablets may be used do not exceed 6 tablets 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 at 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?

1-800-719-9260

Principal Display Panel

Compare to Advil® active ingredient

See New Warnings Information

Ibuprofen Tablets

200 mg

Pain Reliever / Fever Reducer (NSAID)

50 COATED TABLETS

Actual Size



: PD#ST ZD CT

EXP.

LOT NO.





DO NOTUSE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

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*nonsteroidal anti-inflammatory drug

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- toothache backache the common cold menstrual cramps
- temporarily reduces fever

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- hives facial swelling asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters
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- take a blood thinning (anticoagulant) or steroid drug.
- take other drugs containing prescription or non prescription NSAIDs [aspirin, ibuprofen, nap roxen, 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 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, or kidney disease ■you have asthma ■you are taking a diuretic ▶

Drug Facts (continued)

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

taking any other drug

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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)

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adults and children 12 years and older

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7 SELECT IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10202-604

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM) | IBUPROFEN | 200 mg |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |
| HYPROMELLOSES (UNII: 3NXW29 V3WO) | | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|----------|
| Color | BROWN | Score | no score |
| Shape | ROUND | Size | 10 mm |
| Flavor | | Imprint Code | 12 |
| Contains | | | |

Packaging

| # Iten | n Code | Package Description | Marketing Start Date | Marketing End Date |
|-------------|--------------|---------------------|-----------------------------|--------------------|
| 1 NDC:10202 | 2-604-71 1 i | in 1 CARTON | | |
| 1 | 50 |) in 1 BOTTLE | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA072096 | 08/07/2014 | |
| | | | |

Labeler - 7-Eleven (007347602)

Revised: 8/2014 7-Eleven