

MOREBRAND IBUPROFEN- ibuprofen tablet, coated
Moore Medical

Moore Medical Ibuprofen

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID*)

*nonsteroidal antiinflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

- headache ■ toothache ■ backache ■ menstrual cramps
- common cold ■ muscular aches ■ minor arthritis pain

Temporarily reduces fever

Warnings

Allergy alert:

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

- hives ■ skin reddening ■ asthma (wheezing) ■ facial swelling ■ rash ■ shock ■ 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
- 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
- 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 for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present in the painful area
- any new or unexpected symptoms occur

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 specifically 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.

Directions

- **do not use more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

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:

Do not give to children under 12 years of age.

Other information

- read all product information before using
- store at 68-77°F (20-25°C)
- avoid excessive heat 104°F (above 40°C)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

carnauba wax*, corn starch, hypromellose*, iron oxide red, lactose*, magnesium stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, polyvinyl alcohol*, povidone K30*, silicon dioxide, sodium starch glycolate, stearic acid, talc*, titanium dioxide

**may contain*

Questions or comments?

Call 800.234.1464

MooreBrand® Ibuprofen Label

moore medical

Supporting Health and Care

Reorder No.24805

UPN# 0-0607415-24805-0

Moore Brand®

Ibuprofen 200 mg

(NSAID)

200 Packets/2 Tablets

Each Packet Net Wt. 400 mg

For the temporary relief of minor aches and pains associated with the common cold, headache,

toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps and for the reduction of fever.

To Reorder:

Call: 800.234.1464

Fax: 800.944.6667

Online: www.mooremedical.com

Made in USA, China or India

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Supporting Health & Care

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 ■ under a doctor's care for any serious condition
 ■ taking any other drug

Drug Facts (continued)

When using this product

■ take with food or milk. If stomach upset occurs

■ **Do not take** ■ vomit blood ■ have bloody or black stools

■ you experience any of the following signs of stomach bleeding:

■ 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

■ vomit blood or tarry for more than 10 days

■ fever gets worse or lasts for more than 3 days

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■ avoid excessive heat (above 40°C)

■ tamper evident sealed packets

■ do not use any opened or torn packets

Inactive ingredients

carbamide wax, corn starch, hypromellose, iron oxide red, lactose, magnesium stearate, microcrystalline cellulose, polyacrylamide, polyethylene glycol, polyvinyl alcohol, povidone (K-30), silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

*may contain

► **Questions or comments?** Call 800.234.1464

Distributed by:
Moore Medical LLC
Farmington, CT 06032
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MOREBRAND IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55670-850 (NDC:47682-700)
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
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

STEARIC ACID (UNII: 4ELV7Z65AP)

POVIDONE K30 (UNII: U725QWY32X)

Product Characteristics

Color	red (Reddish Brown)	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55670-850-99	2 in 1 PACKET; Type 0: Not a Combination Product	02/04/2019	
2	NDC:55670-850-04	200 in 1 BOX	02/04/2019	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	02/04/2019	

Labeler - Moore Medical (051420107)

Registrant - Unifirst First Aid Corporation (832947092)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		170837962	repack(55670-850) , relabel(55670-850)

Revised: 11/2019

Moore Medical