

IBUPROFEN- ibuprofen tablet
CARDINAL HEALTH

611R Leader Cardinal 70000-0597 Ibuprofen Tablets USP 200 mg

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

children under 12 years

- 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
- ask a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? Call **1-877-290-4008**

LEADER
NDC 70000-0597-2
Ibuprofen
Tablets USP, 200 mg
Pain Reliever
Fever Reducer (NSAID)

100% Money Back Guarantee

100 COATED TABLETS

Read all product information before using. Keep the box for important information. Refer to carton for complete warning information.

Active ingredient (in each tablet) Ibuprofen 200 mg (NSAID)*

Purpose nonsteroidal anti-inflammatory drug

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. **If pregnant or breast-feeding,** ask a health professional before use. **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 ● TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING
● store between 20-25°C (68-77°F)

Questions or comments? Call 1-877-290-4008

DIST. BY CAH DUBLIN OH, 43017 www.myleader.com 1-800-200-6315
100% Money Back Guarantee CIN 5765185 REV. 4/22
©2022 Cardinal Health. MADE IN INDIA

Lot No.: Varnish Omit Area
Exp Date: 611R

Adhesive Area

■ 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

If pregnant or breast-feeding, ask a health professional before use. 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 ■ **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

- store between 20-25°C (68-77°F)

Questions or comments?
 Call 1-877-290-4008

LEADER²

NDC 70000-0597-1

Ibuprofen

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

50 COATED TABLETS

Read all product information before using. Keep the box for important information.

Refer to carton for complete warning information.

Active ingredient (in each tablet) Purpose
Ibuprofen 200 mg (NSAID)* Pain reliever/Fever reducer

* nonsteroidal anti-inflammatory drug

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 ■ wheezing (ng) ■ 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:

Drug Facts (continued under label)

DIST. BY CAH DUBLIN OH, 43017
www.myleader.com 1-800-200-6313

100% Money Back Guarantee
Return to place of purchase if not satisfied.

MADE IN INDIA
©2022 Cardinal Health
CIN 5765193
REV. 4/22

611R

Varnish Omit Area

Lot No.:
PEE
HERE
Exp Date:

Lot No.:
Varnish Omit

Exp Date:



CIN 5765193 REV. 4/22

100% Money Back Guarantee

Return to place of purchase if not satisfied.

MADE IN INDIA 6118

DIST. BY CAH DUBLIN OH, 43017 1-800-200-6313

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc.

©2022 Cardinal Health

Read all product information before using.
Keep the box for important information.

Drug Facts

Active ingredient (in each tablet) Purpose

Ibuprofen 200 mg (NSAID)*... Pain reliever/Fever reducer
*nonsteroidal anti-inflammatory drug

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

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

- 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:

Drug Facts (continued)

- 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	children under 12 years
<ul style="list-style-type: none">take 1 tablet every 4 to 6 hours while symptoms persistif pain or fever does not respond to 1 tablet, 2 tablets may be useddo not exceed 6 tablets in 24 hours, unless directed by a doctor	<ul style="list-style-type: none">ask a doctor

Other information

- store between 20-25°C (68-77°F)

LEADER²

COMPARE TO
MOTRIN[®] IB
active ingredient†

100% Money
Back Guarantee

Actual Size

Ibuprofen

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

50 COATED
TABLETS

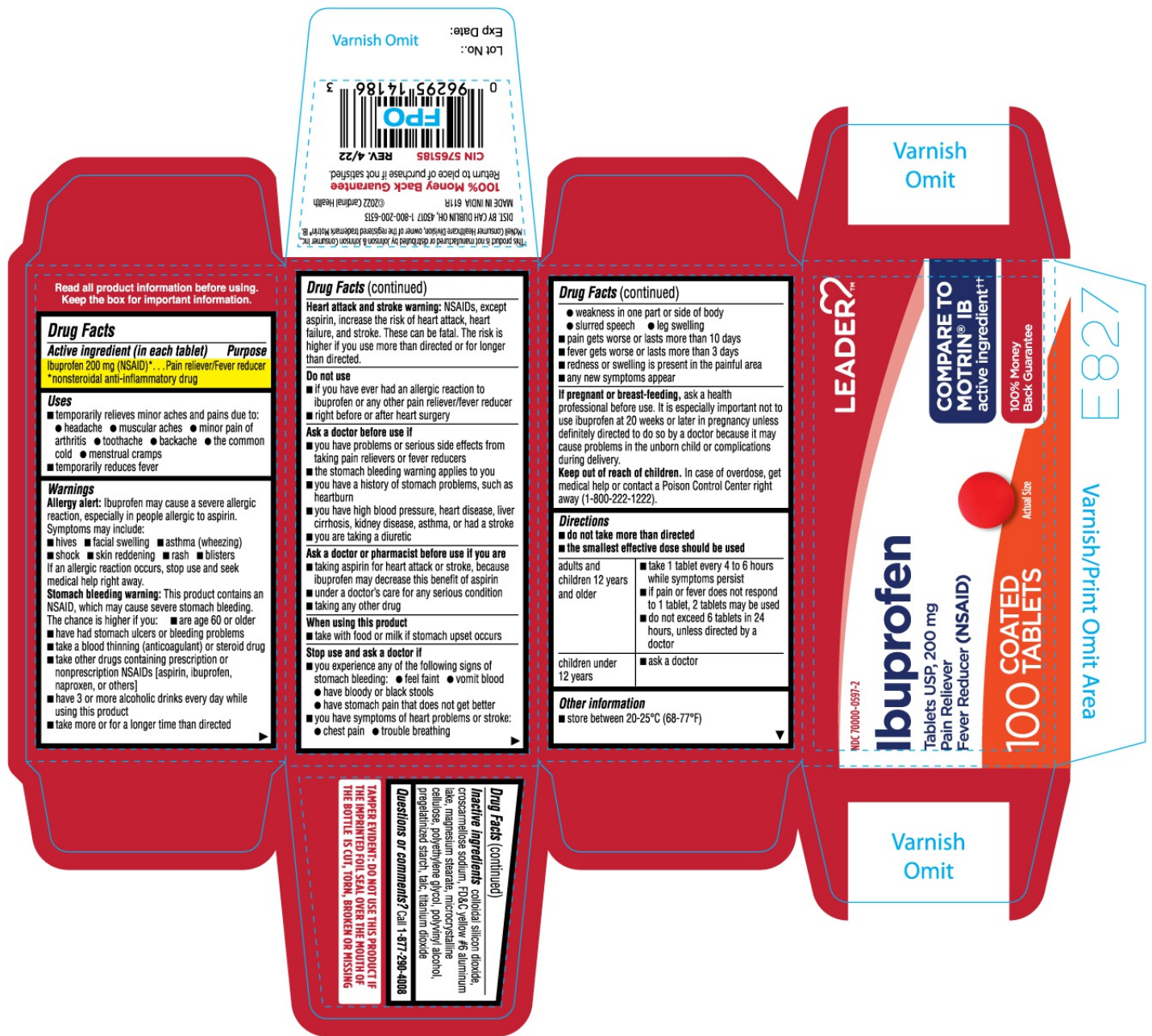
9283 Varnish/Print Omit Area

Drug Facts (continued)

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? Call 1-877-290-4008

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0597
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0597-2	1 in 1 CARTON	05/25/2022	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0597-1	1 in 1 CARTON	05/25/2022	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	05/25/2022	

Labeler - CARDINAL HEALTH (063997360)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(70000-0597)