

IBUPROFEN- ibuprofen tablet
TWIN MED LLC

Twin Med - Procure Ibuprofen Tablets, USP 200 mg (55681-401)

Drug Facts

ACTIVE INGREDIENT (in each tablet/caplet)

Ibuprofen 200 mg (NSAID) *

nonsteroidal anti-inflammatory drug

PURPOSE

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

- store at 20-25°C (68-77°F)[See USP Controlled Room Temperature]
- avoid high humidity and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, iron oxide red, maize starch, poly ethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

QUESTIONS OR COMMENTS?

call toll-free 1-844-912-4012

Distributed by: Twin Med LLC

Santa Fe Springs, CA 90670


www.procureproducts.com

ITEM# PCOTC200 MADE IN INDIA

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC# 55681-401-03

See New Warnings Information

 *Compare to active ingredient in Advil® Caplets IBUPROFEN PAIN RELIEVER FEVER REDUCER (NSAID**)  300 CAPLETS 200 MG	8 15316 017010 NDC 55681-401-03	DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED	Drug Facts
			Active ingredient (in each caplet) <i>Purpose</i> Ibuprofen 200 mg (NSAID**);Pain reliever/Fever reducer *nonsteroidal anti-inflammatory drug
			Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ the common cold ■ muscular aches ■ minor pain of arthritis ■ 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 any other pain reliever/fever reducer ■ right before or after heart surgery
			Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ 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 ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin ■ taking any other drug
			Peel for directions

Drug Facts, (cont'd)
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 (1-800-222-1222) right away.
Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: 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 ■ store between 20°-25°C (68°-77°F) ■ avoid excessive heat above 40°C (104°F)
Inactive ingredients colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide
Questions? call toll-free 1-844-912-4012

IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

Contains no ingredient made from a

gluten-containing grain (wheat, barley, or rye)

Do not use if foil inner seal is broken or missing.

250 Coated Caplets †

†Capsule-Shaped Tablets

Important: Read all product information before using.

Do not use if the foil inner seal is broken or missing

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55681-401
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	red (Reddish Brown)	Score	no score
Shape	OVAL ((Capsule shaped tablet))	Size	14mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-401-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/30/2022	

Labeler - TWIN MED LLC (009579330)

Revised: 1/2024

TWIN MED LLC