

IBUWIN FORTE- ibuprofen tablet
OPMX LLC

Ibuwin Forte

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
 - 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

- the 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 or asthma
- 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 this benefit of aspirin
- taking any other drug

WHEN USING THIS PRODUCT

- take with food or milk if stomach upset occurs
- the risk of heart attack 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
 - have bloody or black stools
 - vomit blood
 - 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.

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)
- avoid high humidity and excessive heat above 40°C (104°F)
- read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL IS BROKEN OR MISSING

INACTIVE INGREDIENTS

colloidal silicon dioxide, corn starch, hypromellose, iron oxide red, lactose monohydrate, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

QUESTIONS OR COMMENTS?

Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opmx.us>

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69729-157-10

Ibuwin Forte

Ibuprofen 200 mg

Pain Reliever/Fever Reducer (NSAID)

Analgésico/Antipirético (AINE)

10 Tablets/Tabletas

REV. 12.2023 ITEM # RRX1137
 8 10053 18141 6
 Exclusively distributed by:
 P M X
 Chula Vista, CA 91910
 Phone: 619-600-5632



10 Tablets

**Pain Reliever / Fever Reducer
 (NSAID)**
**Analgesico / Antipirético
 (AINE)**



Ibuwin Forte

Ibuprofen 200 mg

Ibuwin Forte
 Ibuprofen 200 mg



NDC 69729-157-10

CONSULTE LA INFORMACIÓN EN ESPAÑOL EN EL INTERIOR DEL EMPAQUE

Ibuwin Forte

Ibuprofeno 200 mg



Lot: _____
 Exp. date: _____
 NO VANISH AREA

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 ■ 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 ■ the 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 or asthma ■ 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 this benefit of aspirin ■ 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 ■ have bloody or black stools ■ vomit blood
 ■ 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.

Directions
 ■ do not take more than directed
 ■ the smallest effective dose should be used
Adults and children 12 years and over
 ■ 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
 ■ store at 20° to 25°C (68° to 77°F)
 ■ avoid excessive heat above 40°C (104°F)
 ■ read all product information before using
 ■ TAMPER EVIDENT. DO NOT USE IF IMPRINTED SAFETY SEAL IS BROKEN OR MISSING
Inactive ingredients colloidal silicon dioxide, corn starch, hypromellose, iron oxide red, lactose monohydrate, povidone K30, sodium starch glycolate, stearic acid, titanium dioxide, triacetin
Questions or comments?
 Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opm.us>

NO VANISH AREA

IBUWIN FORTE
 ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-157
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-157-10	1 in 1 CARTON	12/29/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	12/29/2023	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	label(69729-157) , manufacture(69729-157)

Revised: 12/2023

OPMX LLC