

IBUPROFEN- ibuprofen tablet, film coated
Northwind Health Company, LLC

Active ingredient (in each brown tablet)

Ibuprofen USP, 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:

- shock
- hives
- facial swelling
- asthma (wheezing)
- 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

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 - leg swelling
 - slurred speech - weakness in one part or side of body
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- fever gets worse or lasts more than 3 days
- any new 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 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 use 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 take more than 6 tablets 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 40°C (104°F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, cellulose, corn starch, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-540-3765

Package label

NDC: 51655-354-26



IBUPROFEN			
ibuprofen tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51655-354(NDC:57896-941)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-354-26	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	05/27/2020	

Labeler - Northwind Health Company, LLC (036986393)

Registrant - Northwind Health Company, LLC (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Health Company, LLC		036986393	repack(51655-354)

