

ADVIL MENSTRUAL PAIN- ibuprofen sodium tablet, coated
Pfizer Consumer Healthcare

Advil® Menstrual Pain

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (provided as ibuprofen sodium 256 mg) (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - menstrual cramps
 - backache
 - headache
 - muscular aches
 - the common cold
 - toothache
 - 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 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
 - 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 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

- **each tablet contains:** sodium 22 mg
- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

acesulfame potassium, caramel color, carnauba wax, colloidal silicon dioxide, copovidone, ferric oxide, hypromellose, mannitol, medium-chain triglycerides, microcrystalline cellulose, natural and artificial flavor, pharmaceutical ink, polyethylene glycol, propylene glycol, sodium lauryl sulfate, sucralose, titanium dioxide

Questions or comments?

Call weekdays 9 AM to 5 PM EST at **1-800-88-ADVIL**

For most recent product information, visit www.Advil.com

PRINCIPAL DISPLAY PANEL - 40 Tablet Bottle Label

Advil®

menstrual

PAIN

Ibuprofen Tablets, 200 mg

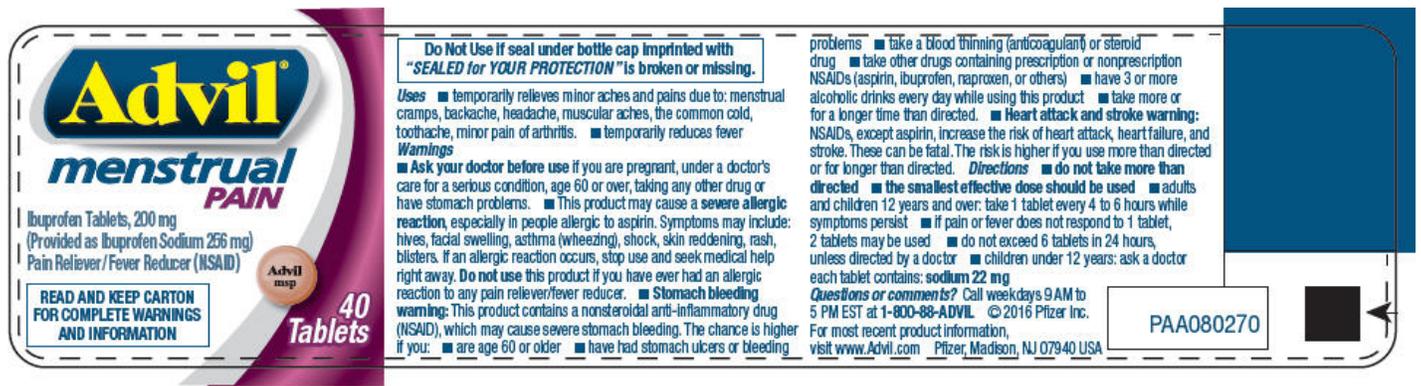
(Provided as Ibuprofen Sodium 256 mg)

Pain Reliever / Fever Reducer (NSAID)

**READ AND KEEP CARTON
FOR COMPLETE WARNINGS
AND INFORMATION**

40

Tablets



PRINCIPAL DISPLAY PANEL - 40 Tablet Bottle Carton

**FILM-COATED
IBUPROFEN
SODIUM**

Advil®

**menstrual
PAIN**

**Ibuprofen Tablets, 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)**

Tablets

40 Tablets

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN SODIUM (UNII: RM1CE97Z4N) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN SODIUM	256 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE (UNII: D9C330MD8B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (beige)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	Advil;msp
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0230-20	1 in 1 CARTON	07/01/2016	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0230-40	1 in 1 CARTON	07/01/2016	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA201803	06/30/2016	

Labeler - Pfizer Consumer Healthcare (828831730)

Establishment			
Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company		829390975	ANALYSIS(0573-0230) , LABEL(0573-0230) , MANUFACTURE(0573-0230) , PACK(0573-0230)

Revised: 10/2016

Pfizer Consumer Healthcare