# ADVIL- ibuprofen tablet coated tablet, coated Lil' Drug Store Products, Inc.

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### ADVIL- ibuprofen tablet, coated

### **Drug Facts**

**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:
- 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 non-prescription 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 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.

### **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

- •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**

acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, white wax

# **Questions or comments?**

call toll free 1-800-88-ADVIL

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#### **Advil**

Ibuprofen Tablets, 200mg

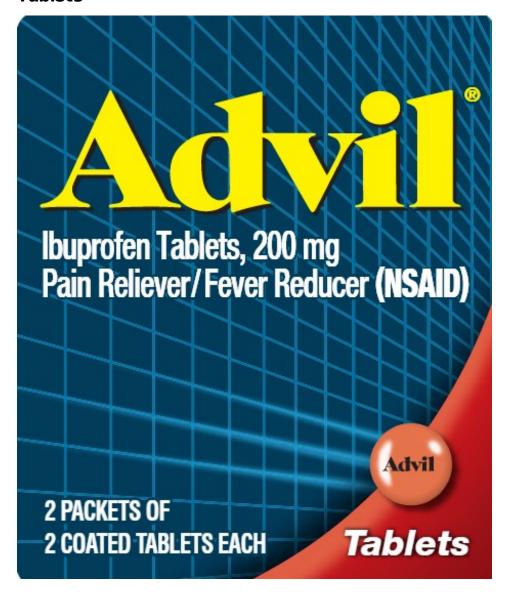
Pain Reliever/Fever Reducer (NSAID)

2 Packets of

2 Coated Tablets Each

### **Advil**

#### **Tablets**



### **Advil**

Ibuprofen Tablets, 200mg

Pain Reliever/Fever Reducer (NSAID)

3 Packets of

2 Coated Tablets Each

### **Advil**

#### **Tablets**



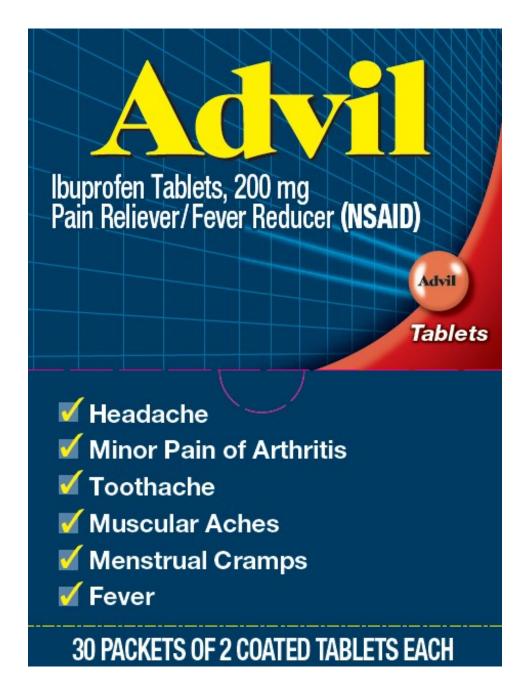
### **Advil**

Ibuprofen Tablets, 200mg

Pain Reliever/Fever Reducer (NSAID)

- Headache
- Minor Pain of Arthritis
- Toothache
- Muscular Aches
- Menstrual Cramps
- Fever

**30 PACKETS OF 2 COATED TABLETS EACH** 



### **CVP 4 Count Carton**

### **Advil**

Ibuprofen Tablets, 200mg

Pain Reliever/Fever Reducer (NSAID)

[pill image]

**Tablets** 

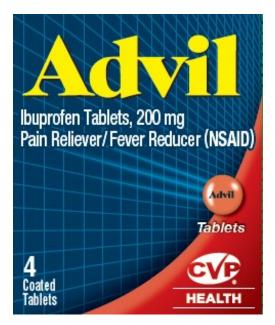
4

Coated

**Tablets** 

**CVP** 

### **HEALTH**



# **ADVIL**

ibuprofen tablet coated tablet, coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:29485-1005

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI100M) (IBUPROFEN - UNII: WK2XYI100M)	IBUPROFEN	200 mg

Inactive Ingredients			
Ingredient Name	Strength		
FERRIC OXIDE RED (UNII: 1K09F3G675)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
METHYLPARABEN (UNII: A218C7H19T)			
SHELLAC (UNII: 46N107B710)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
SUCROSE (UNII: C151H8M554)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WHITE WAX (UNII: 7G1J5DA97F)			
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics				
Color brown Score no score				
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	ADVIL	
Contains				

# Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:294851005-4 2 in 1 BLISTER PACK 04/30/2002 11/18/2025

2 in 1 POUCH; Type 0: Not a Combination Product

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA018989	04/30/2002	11/18/2025		

# **ADVIL**

ibuprofen tablet coated tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6749	
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			
FERRIC OXIDE RED (UNII: 1K09F3G675)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
SHELLAC (UNII: 46N107B710)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics				
Color brown Score no score				
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	ADVIL	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 6749-6	3 in 1 BLISTER PACK	02/06/2017	11/07/2025		
1		2 in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date					
NDA	NDA018989	02/06/2017	11/07/2025		

# ADVIL

ibuprofen tablet coated tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-7012
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients		
	Ingredient Name	Strength

FERRIC OXIDE RED (UNII: 1K09F3G675) **SODIUM BENZOATE** (UNII: OJ245FE5EU) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) METHYLPARABEN (UNII: A2I8C7HI9T) **SHELLAC** (UNII: 46N107B710) CROSCARMELLOSE SODIUM (UNII: M280L1HH48) PROPYLPARABEN (UNII: Z8IX2SC10H) **SODIUM LAURYL SULFATE (UNII: 368GB5141J)** SILICON DIOXIDE (UNII: ETJ7Z6XBU4) STARCH, CORN (UNII: O8232NY3SJ) SUCROSE (UNII: C151H8M554) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) WHITE WAX (UNII: 7G1J5DA97F) **DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)** POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) **STEARIC ACID** (UNII: 4ELV7Z65AP)

Product Characteristics				
Color brown Score no score				
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	ADVIL	
Contains				

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:29485- 7012-3	30 in 1 BOX	11/01/2016	12/31/2025			
1		2 in 1 POUCH; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA018989	11/01/2016	12/31/2025	

### **ADVIL**

ibuprofen tablet coated tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6500	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		

Inactive Ingredients			
Ingredient Name	Strength		
FERRIC OXIDE RED (UNII: 1K09F3G675)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
SHELLAC (UNII: 46N107B710)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
SUCROSE (UNII: C151H8M554)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WHITE WAX (UNII: 7G1J5DA97F)			
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics					
Color brown Score no score					
Shape	OVAL	Size	15mm		
Flavor		Imprint Code	ADVIL		
Contains	Contains				

I	Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 6500-4	2 in 1 BLISTER PACK	08/17/2017	12/31/2025		
1		2 in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date D				
NDA	NDA018989	08/17/2017	12/31/2025	

Revised: 12/2023 Lil' Drug Store Products, Inc.