ADVIL- ibuprofen sodium tablet, coated
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (provided as ibuprofen sodium 256 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
- 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

- each tablet contains: **sodium 22 mg**
- read all warnings and directions before use.
- 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**

Additional Information

Do Not Use if the sealed child resistant pouch is broken or torn.

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

For US Patent or Application status see www.productpats.com

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

PRINCIPAL DISPLAY PANEL

NDC 0573-0133-02

Advil

FILM-COATED
IBUPROFEN
SODIUM

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

Advil Tablets

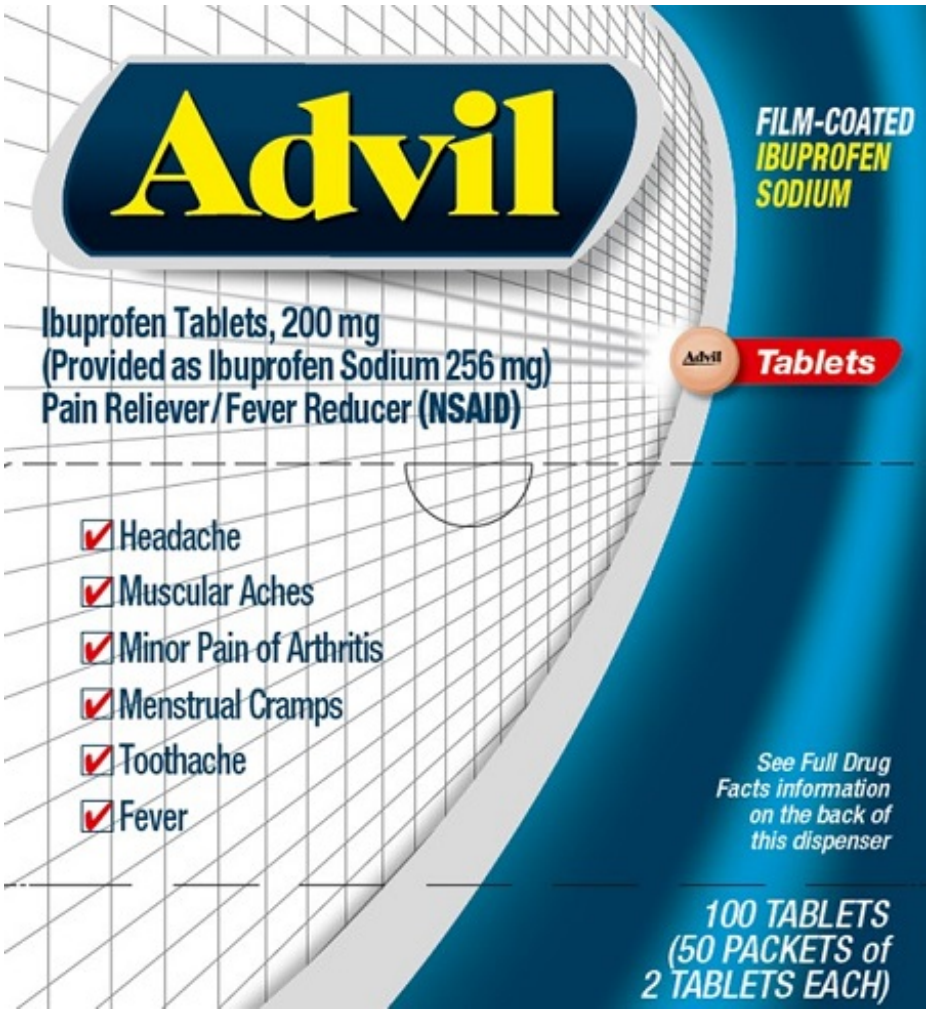
- **Headache**
- **Muscular Aches**
- **Minor Pain of Arthritis**
- **Menstrual Cramps**
- **Toothache**
- **Fever**

See Full Drug Facts information on the back of this dispenser

100 TABLETS

(50 PACKETS of 2 TABLETS EACH)

000068427 Front Carton



PRINCIPAL DISPLAY PANEL

Advil ®

20
FREE
TABLETS

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

FILM-COATED
IBUPROFEN
SODIUM

Advil Tablets

100
Tablets

ADVIL
ibuprofen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0133
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)	
CARAMEL (UNII: T9D99G2B1R)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

COPOVIDONE K25-31 (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: 3WQ0SDW1A)	
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;asymmetrical;underline
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0133-20	1 in 1 CARTON	07/08/2013	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0133-40	1 in 1 CARTON	07/08/2013	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0133-80	1 in 1 CARTON	07/08/2013	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0133-02	50 in 1 TRAY	07/08/2013	
4		2 in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:0573-0133-04	2 in 1 BLISTER PACK	07/08/2013	
5		2 in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:0573-0133-89	1 in 1 CARTON	07/08/2013	
6		160 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0133-81	1 in 1 CARTON	07/08/2013	
7		100 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-0133-05	2 in 1 CARTON	07/08/2013	
8		2 in 1 PACKET; Type 0: Not a Combination Product		

9	NDC:0573-0133-88	2 in 1 PACKAGE	07/08/2013	
9		120 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0573-0133-41	1 in 1 CARTON	08/12/2015	
10		40 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:0573-0133-91	1 in 1 CARTON	12/01/2014	
11		180 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:0573-0133-01	3000 in 1 CASE	08/11/2014	
12		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA201803	07/08/2013	

ADVIL

ibuprofen sodium tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0134
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)	
CARAMEL (UNII: T9D99G2B1R)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (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: 3WQ0SDW1A)	

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	OVAL	**Size**	15mm
Flavor		**Imprint Code**	Advil;asymmetrical;underline
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0134-20	1 in 1 CARTON	07/08/2013	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0134-80	1 in 1 CARTON	07/08/2013	
2		80 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	07/08/2013	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC