

ADVIL- ibuprofen capsule, liquid filled
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*
(present as the free acid and potassium salt)

*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 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: **potassium 20 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

Advil Liqui-Gels

FD&C green no. 3, gelatin, lecithin (soybean), medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

Advil Liqui-Gels Minis

FD&C green no. 3, gelatin, medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

Questions or comments?

call toll free **1-800-88-ADVIL**

PRINCIPAL DISPLAY PANEL

Advil®

LIQUI•GELS®

Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (**NSAID**)

20
Liquid Filled
Capsules

000068421 Front Carton



PRINCIPAL DISPLAY PANEL- 160 Capsule Bottle Label

- Easy Open
ARTHRITIS CAP

Arthritis Foundation
Ease of
UseSM
CAP

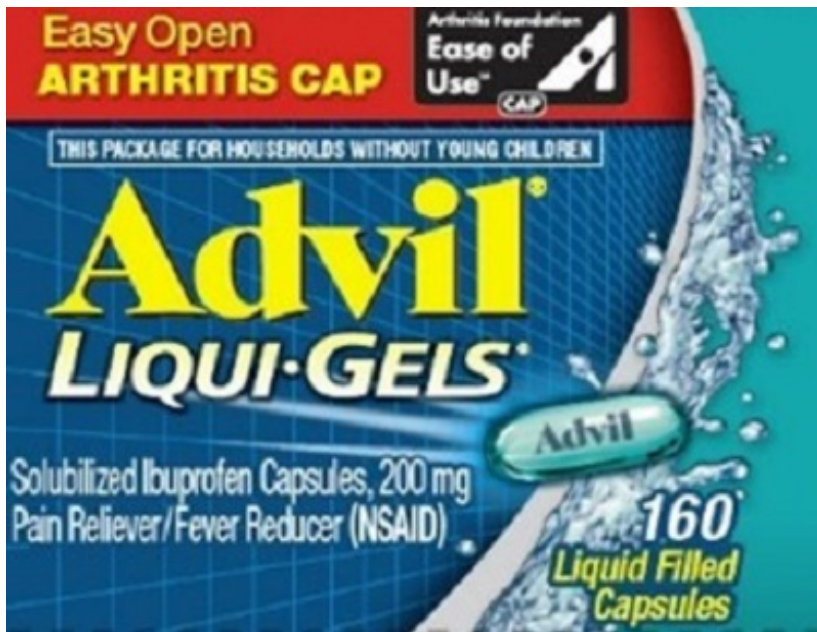
THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Advil®
LIQUI•GELS®

Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (**NSAID**)

160

**Liquid Filled
Capsules**



PRINCIPAL DISPLAY PANEL

***Smaller
Capsule***

***Same
Strength****

***Advil®
LIQUI-GELS®***

minis

Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (**NSAID**)

***20
Liquid Filled
Capsules***

000068424 Front Carton

Advil[®]
LIQUI-GELS[®]

Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (NSAID)

minis

Advil

20
Liquid Filled Capsules

Smaller Capsule

Same Strength*

*Compared to Advil[®] Liqui-Gels[®]

ADVIL

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0169
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
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	

SORBITAN (UNII: 6O92ICV9RU)

SORBITOL (UNII: 506T60A25R)

Product Characteristics

Color	green (Transparent green to blue green)	Score	no score
Shape	CAPSULE (oblong softgel)	Size	20mm
Flavor		Imprint Code	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0169-17	3000 in 1 CASE	04/10/1995	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0573-0169-02	50 in 1 BOX	04/10/1995	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0573-0169-19	1 in 1 CARTON	04/10/1995	
3		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0573-0169-20	1 in 1 CARTON	04/10/1995	
4		20 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0169-40	1 in 1 CARTON	04/10/1995	
5		80 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0169-11	1 in 1 CARTON	04/10/1995	
6		120 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0169-89	1 in 1 CARTON	04/10/1995	
7		160 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-0169-30	1 in 1 CARTON	04/10/1995	
8		40 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0573-0169-31	1 in 1 CARTON	04/10/1995	
9		60 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0573-0169-86	1 in 1 CARTON	04/10/1995	
10		100 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:0573-0169-51	1 in 1 CARTON	04/10/1995	

11		180 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:0573-0169-43	1 in 1 CARTON	04/10/1995	
12		120 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:0573-0169-49	200 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/1995	
14	NDC:0573-0169-52	1 in 1 CARTON	04/10/1995	
14		200 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:0573-0169-08	2 in 1 CARTON	04/10/1995	
15		120 in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:0573-0169-22	1 in 1 CARTON	04/10/1995	
16		30 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:0573-0169-13	240 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/1995	
18	NDC:0573-0169-76	1 in 1 CARTON	04/10/1995	
18		160 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	NDA020402	04/10/1995	

ADVIL

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0149
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
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green (Transparent green to blue green)	Score	no score
Shape	CAPSULE (oblong softgel)	Size	20mm
Flavor		Imprint Code	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0149-13	1 in 1 CARTON	04/10/1995	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0149-04	2 in 1 BLISTER PACK	03/01/2018	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0573-0149-66	160 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	
4	NDC:0573-0149-91	180 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020402	04/10/1995	

ADVIL

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-1769
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
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green (transparent green to blue green)	Score	no score
Shape	CAPSULE (oblong softgel)	Size	13mm
Flavor		Imprint Code	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-1769-20	1 in 1 CARTON	03/08/2017	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-1769-80	1 in 1 CARTON	03/08/2017	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-1769-89	1 in 1 CARTON	03/08/2017	
3		160 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-1769-14	240 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
5	NDC:0573-1769-13	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	
6	NDC:0573-1769-09	1 in 1 BLISTER PACK	06/01/2018	
6		8 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020402	03/08/2017	

