

**ADVIL- ibuprofen capsule, liquid filled**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) 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 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 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 - 40 Capsule Bottle Carton**

**0573-0169-30**

**Advil®**

**LIQUI•GELS®**

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

**40**

***Liquid Filled***

***Capsules***



**PRINCIPAL DISPLAY PANEL - 160 Capsule Bottle Label**

0573-0149-66

**Easy Open  
ARTHRITIS CAP**  
**Arthritis Foundation  
Ease of  
Use  
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***



**Easy Open ARTHRITIS CAP** 

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

# Advil LIQUI-GELS

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

**160** Liquid Filled Capsules

**Drug Facts**

**Active ingredient (in each capsule) Purpose**  
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)\* .....Pain reliever/Fever reducer (present as the free acid and potassium salt)  
\*nonsteroidal anti-inflammatory drug

**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

PAAC00146

FPO

L 3 0573 0149 66 2

LIFT HERE for opening instructions

**Drug Facts (continued)**

**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 redness
- 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 strokes. 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

**Drug Facts (continued)**

**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

**Drug Facts (continued)**

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 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
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

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

**Questions or comments?**  
call toll free 1-800-83-ADVIL

# Advil

For most recent product information, visit [www.Advii.com](http://www.Advii.com)

Distributed by: Pfizer, Madison, NJ 07940 USA

© 2016 Pfizer Inc.

LIQUI-GELS® is a trademark or registered trademark of Catalent Pharma Solutions.

**PRINCIPAL DISPLAY PANEL - 20 Capsule Bottle Carton**

0573-1769-20

**Smaller Capsule**

**Same Strength\***

**Advil®**  
**LIQUI•GELS®**

***minis***

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

**20**  
***Liquid Filled***  
***Capsules***

\*Compared to Advil® Liqui-Gels®





<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-0169
<b>Route of Administration</b>	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: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

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

### 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: 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:0573-0149-13	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: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	
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

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

### 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	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

### Establishment

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company		829390975	ANALYSIS(0573-0149, 0573-0169, 0573-1769) , LABEL(0573-0149, 0573-0169, 0573-1769) , MANUFACTURE(0573-0149, 0573-0169, 0573-1769) , PACK(0573-0149, 0573-0169, 0573-1769)

Revised: 11/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC