

ADVIL- ibuprofen capsule, liquid filled
Pfizer Consumer Healthcare

Advil Liqui-Gels (ibuprofen)

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

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, or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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

FD&C green no. 3, gelatin, light mineral oil, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

QUESTIONS OR COMMENTS?

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

PRINCIPAL DISPLAY PANEL - 80 Capsule Bottle Label

Advil®
LIQUI-GELS®

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

80 Liquid Filled
Capsules

Liquid Filled
Capsules

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

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80 Liquid Filled
Capsules

Liquid Filled
Capsules

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

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

Uses

- temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.
- temporarily reduces fever

Warnings

- Ask your doctor before use** if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
- This product 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. **Do not use** this product if you have ever had an allergic reaction to any pain reliever/fever reducer.
- Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (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.

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

Each capsule contains: potassium 20 mg

Questions or comments? call toll free 1-800-88-ADVIL

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

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PAA021542

PRODUCT PACKAGING

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

Advil Liqui-Gels

Solubilized Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

80 Liqui-Gels* *Liquid Filled Capsules

Liquid Filled Capsules

Distributed by: Pfizer

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

Advil[®]

LIQUI-GELS[®]


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

80 Liqui-Gels[®]*
*Liquid Filled Capsules




Liquid Filled Capsules


128 code #021543




128 code #021543



128 code #021543



128 code #021543



READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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, or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - red stool
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- numbness 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 Advil Liqui-Gels[®] unless a health professional definitely advises to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

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
- children under 12 years: ask a doctor

Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use.
- keep at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C green no. 3, gelatin, light mineral oil, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?
call toll free 1-800-99-ADVIL

Drug Facts (continued)

Purpose

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
 - backache
 - the common cold
 - 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
- dizziness

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 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

Do Not Use If Seal Under Bottle Cap Imprinted With "SEAL" For Your Protection Is Broken or Missing.

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

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80 Liqui-Gels[®]
Liquid Filled Capsules

ADVIL

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0573-0169
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3	
GELATIN	
LIGHT MINERAL OIL	
POLYETHYLENE GLYCOLS	
POTASSIUM HYDROXIDE	
SORBITAN	
SORBITOL	
WATER	

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		
1		2 in 1 POUCH; Combination Product Type = C112160		
2	NDC:0573-0169-02	50 in 1 BOX		
2		2 in 1 POUCH; Combination Product Type = C112160		
3	NDC:0573-0169-19	1 in 1 CARTON		
3		4 in 1 BLISTER PACK; Combination Product Type = C112160		
4	NDC:0573-0169-20	1 in 1 CARTON		
4		20 in 1 BOTTLE; Combination Product Type = C112160		
5	NDC:0573-0169-40	1 in 1 CARTON		
5		80 in 1 BOTTLE; Combination Product Type = C112160		
6	NDC:0573-0169-11	1 in 1 CARTON		
6		120 in 1 BOTTLE; Combination Product Type = C112160		
7	NDC:0573-0169-89	1 in 1 CARTON		
7		160 in 1 BOTTLE; Combination Product Type = C112160		
8	NDC:0573-0169-30	1 in 1 CARTON		
8		40 in 1 BOTTLE; Combination Product Type = C112160		
9	NDC:0573-0169-31	1 in 1 CARTON		
9		60 in 1 BOTTLE; Combination Product Type = C112160		
	NDC:0573-0169-			

10	NDC:0573-0169-86	1 in 1 CARTON		
10		100 in 1 BOTTLE; Combination Product Type = C112160		
11	NDC:0573-0169-51	1 in 1 CARTON		
11		180 in 1 BOTTLE; Combination Product Type = C112160		
12	NDC:0573-0169-43	1 in 1 CARTON		
12		120 in 1 BOTTLE; Combination Product Type = C112160		
13	NDC:0573-0169-49	200 in 1 BOTTLE; Combination Product Type = C112160		
14	NDC:0573-0169-52	1 in 1 CARTON		
14		200 in 1 BOTTLE; Combination Product Type = C112160		
15	NDC:0573-0169-08	2 in 1 CARTON		
15		120 in 1 BOTTLE; Combination Product Type = C112160		
16	NDC:0573-0169-22	1 in 1 CARTON		
16		30 in 1 BOTTLE; Combination Product Type = C112160		
17	NDC:0573-0169-13	240 in 1 BOTTLE; Combination Product Type = C112160		

Marketing Information

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

Labeler - Pfizer Consumer Healthcare (828831730)

Establishment

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

Revised: 9/2014

Pfizer Consumer Healthcare