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**

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)

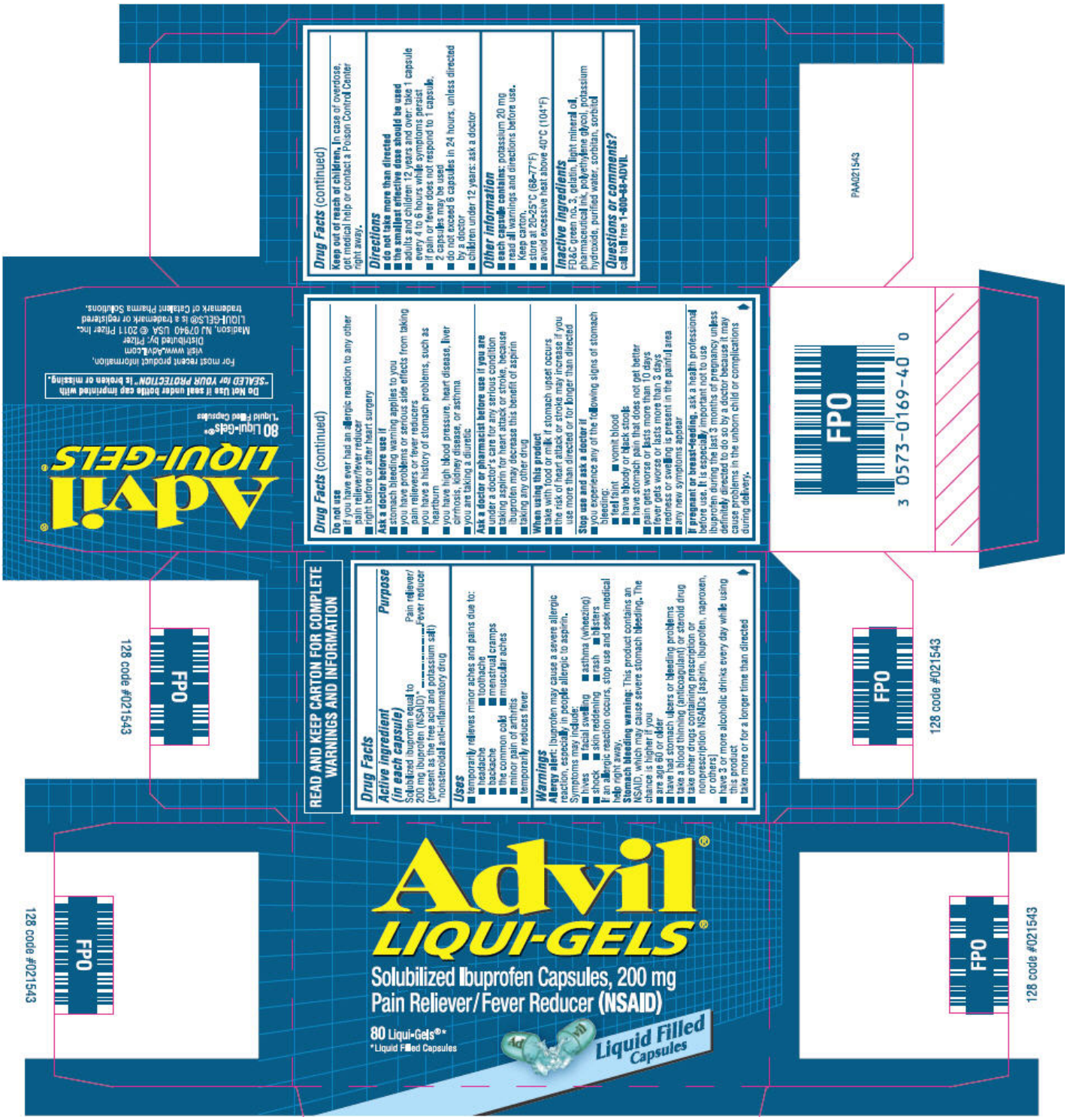
80 Liqui-Gels* *Liquid Filled Capsules

Liquid Filled Capsules

Distributed by: Pfizer

Madison, NJ 07940 USA ©2011 Pfizer Inc.

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



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		
2	NDC:0573-0169-02	50 in 1 BOX		
2		2 in 1 POUCH		
3	NDC:0573-0169-19	1 in 1 CARTON		
3		4 in 1 BLISTER PACK		
4	NDC:0573-0169-20	1 in 1 CARTON		
4		20 in 1 BOTTLE		
5	NDC:0573-0169-40	1 in 1 CARTON		
5		80 in 1 BOTTLE		
6	NDC:0573-0169-11	1 in 1 CARTON		
6		120 in 1 BOTTLE		
7	NDC:0573-0169-89	1 in 1 CARTON		
7		160 in 1 BOTTLE		
8	NDC:0573-0169-30	1 in 1 CARTON		
8		40 in 1 BOTTLE		
9	NDC:0573-0169-31	1 in 1 CARTON		
9		60 in 1 BOTTLE		
10	NDC:0573-0169-86	1 in 1 CARTON		
10		100 in 1 BOTTLE		
11	NDC:0573-0169-51	1 in 1 CARTON		
11		180 in 1 BOTTLE		
12	NDC:0573-0169-43	1 in 1 CARTON		
12		120 in 1 BOTTLE		

13	NDC:0573-0169-49	200 in 1 BOTTLE		
14	NDC:0573-0169-52	1 in 1 CARTON		
14		200 in 1 BOTTLE		

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
Catalent Pharma Solutions, LLC		051762268	ANALYSIS(0573-0169), MANUFACTURE(0573-0169), PACK(0573-0169), REPACK(0573-0169)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Argentina S.A.I.C.		970545174	MANUFACTURE(0573-0169)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Richmond, Inc.		969523245	ANALYSIS(0573-0169), LABEL(0573-0169), MANUFACTURE(0573-0169), PACK(0573-0169), RELABEL(0573-0169), REPACK(0573-0169)

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: 10/2012 Pfizer Consumer Healthcare