

IBUPROFEN- ibuprofen capsule, liquid filled AAFES/Your Military Exchanges

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
 - muscular aches
 - minor pain of arthritis
 - toothache
 - backache
 - the common cold
 - menstrual cramps
- 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

- the 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
 - slurred speech
 - leg swelling
 - trouble breathing
 - weakness in one part or side of body
- 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 (1-800-222-1222) 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° to 25°C (68°to 77°F)
- avoid excessive heat above 40°C (104°F) Protect from light
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

FD&C #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitan solution, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare To The Active Ingredient of Advil® Liqui-Gels® †

Ibuprofen

SOLUBILIZED CAPSULES, 200 MG (NSAID)

Liquid filled softgels

Pain reliever/Fever reducer

Softgels**

(**Liquid-Filled Capsules)

**TAMPER-EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT
INFORMATION.**

†This product is not manufactured or distributed by GlaxoSmithKline Consumer
Healthcare Holdings (US) LLC, distributor of Advil® Liquid Gels.

Manufactured For Your Military Exchange

Distributed by:

PL Developments

200 Hicks Street Westbury, NY 11590

Product Label

Exp. Date:

Lot No.:



PL Developments
200 Hicks Street
Westbury, NY 11590

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Uses ■ temporarily relieves minor aches and pains
due to: ■ headache ■ muscular aches ■ minor
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common cold ■ menstrual cramps ■ temporarily
reduces fever

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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

Drug Facts (continued)

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or after heart surgery

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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

Drug Facts (continued)

■ store between 20° to 25°C (68° to 77°F) ■ avoid
excessive heat above 40°C (104°F). Protect from light.
■ swallow whole; do not crush, chew, or dissolve

Inactive ingredients FD&C green #3, gelatin,
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potassium hydroxide, purified water, sorbitol sorbitan
solution, white ink

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TAMPED EVIDENCE, DO NOT USE IF PRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
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WARNINGS AND PRODUCT INFORMATION.

Drug Facts (continued)

symptoms of heart problems or stroke: ■ chest
pain ■ slurred speech ■ leg swelling ■ trouble
breathing ■ weakness in one part or side of body
■ 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
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before use. It is especially important not to use ibuprofen
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exchange select

Compare To The Active Ingredient
of Advil® Liqui-Gels®

Ibuprofen

SOLUBILIZED CAPSULES, 200 mg
Liquid filled softgels
Pain reliever/Fever reducer
(NSAID)
20 Softgels**
(*Liquid Filled Capsules)

Capsules
Actual Size

quality value

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55301-745

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
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	PC16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55301-745-20	1 in 1 BOX	03/31/2018	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55301-745-80	1 in 1 BOX	03/31/2018	
2		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206568	03/31/2018	

Labeler - AAFES/Your Military Exchanges (001695568)