

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-402/SCM-001/S-002/S-003/S-004/S-005

FINAL PRINTED LABELING

Active Ingredient (in each green oblong capsule): Solubilized ibuprofen equal to 200 mg ibuprofen (present as the free acid and potassium salt) **Purpose:** Pain Reliever/Fever Reducer

Uses: Temporarily relieves minor aches and pains associated with:

- Common Cold
- Backache
- Headache
- Minor Pain of Stomach
- Arthritis
- Muscular Aches
- Menstrual Cramps

Temporarily reduces fever

Warnings:
Allergy Alert: If, after taking a pain reliever or fever reducer, you have ever had:

- Hives
- Facial Swelling
- Asthma
- Shock

Do not take Advil. You may have a serious reaction.
Alcohol Warning: If you generally consume 3 or more alcohol-containing drinks a day, you should consult your physician for advice on when and how you should take Advil Liqui-Gels® or other pain relievers.

Do Not Use:
 • With any other pain reliever/fever reducer

- With any other product containing ibuprofen
- For more than 3 days for fever
- For more than 10 days for pain

Ask a Doctor Before Use If:

- The painful area is red or swollen
- You take other drugs on a regular basis
- You are under a doctor's care for any continuing medical condition
- You have had problems or side effects with any pain reliever/fever reducer

Stop Using This Product and Ask A Doctor If:

- Symptoms continue or worsen
- Stomach pain occurs with use of this product
- Any new or unexpected symptoms occur

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. **IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO**

DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center right away.

Directions:
Adults:
 1. Take 1 capsule every 4 to 6 hours while symptoms persist.
 2. If pain or fever does not respond to 1 capsule, 2 capsules may be used, but do not exceed 6 capsules in 24 hours, unless directed by a doctor.
 3. The smallest effective dose should be used.
Children: Do not give to children under 12 unless directed by a doctor.

Read all warnings and directions before use. Keep safe.
 Questions? Call 1-800-58-ADVIL



0169-05/30

Advil®

4 Liqui-Gel® Capsules

SOLUBILIZED IBUPROFEN CAPSULES, 200 mg

5



NEW

Advil®

SOLUBILIZED IBUPROFEN CAPSULES, 200 mg

Advil® 4 Liqui-Gel® Capsules
 SOLUBILIZED IBUPROFEN CAPSULES, 200 mg

Advil **Liqui-Gels®**
 4 Liqui-Gel® Capsules **Pain Reliever / Fever Reducer**
advanced medicine for pain™

THE SEALED IMPRINTED BLISTER PACKS ARE YOUR ASSURANCE THAT THIS PACKAGE HAS NOT BEEN OPENED.
 Inactive Ingredients: FD&C Green No. 3, Gelatin, Polyethylene Glycol, Potassium Hydroxide, Purified Water, Sorbitan, Sorbitol, Titanium Oxide.

Store at room temperature 59-86°F (15-30°C). Avoid excessive heat 104°F (40°C).
 Distributed by WHITEHALL-ROBINS HEALTHCARE, Madison, NJ 07940 Made in U.S.A.

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 U.S. Patent Nos. 5,071,643 and 5,360,615
 By arrangement with R.P. Scherer Corp.

Liqui-Gels® is a trademark of R.P. Scherer Corp.

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← 45.00 →

Advil

Pain Reliever, Fever Reducer
WARNING: Allergy Alert!
If you have had an allergic
reaction to a pain reliever
or fever reducer, read
insert before using.

Distributed by
WHITEHALL-ROBINS
HEALTHCARE
Madison NJ 07940

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HEALTHCARE
Madison NJ 07940

EXP
LOT

PEEL & PUSH

PEEL & PUSH

EXP
LOT

75.00

Advil

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Madison NJ 07940

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Consumer Labeling Leaflet for Advil® Liqui-gels

- ▲ Read all product information before using.
Keep Leaflet for important information.

Advil

Active Ingredient

(in each green oblong capsule):

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

Purpose:

Pain Reliever/Fever Reducer

Uses: Temporarily relieves minor aches and pains associated with:

- Common cold
- Headache
- Toothache
- Muscular Aches
- Backache
- Minor Pain of Arthritis
- Menstrual Cramps

Temporarily reduces fever.

Warnings

Allergy Alert: If, after taking a pain reliever or fever reducer, you have ever had:

- Hives
- Facial swelling
- Asthma
- Shock

Do not take Advil. You may have a serious reaction.

Alcohol Warning: If you generally consume 3 or more alcohol-containing drinks a day, you should consult your physician for advice on when and how you should take Advil Liqui-gels or other pain relievers.

Do Not Use:

- With any other pain reliever/fever reducer
- With any other product containing ibuprofen
- For more than 3 days for fever
- For more than 10 days for pain

Ask a Doctor Before Use If:

- The painful area is red or swollen
- You take other drugs on a regular basis
- You are under a doctor's care for any continuing medical condition
- You have had problems or side effects with any pain reliever/fever reducer

Stop Using This Product and Ask a Doctor If:

- Symptoms continue or worsen
- Stomach pain occurs with use of this product
- Any new or unexpected symptoms occur

ATTACHMENT 1

Continued From Front

Advil

Solubilized Ibuprofen Capsules 200 mg

Warnings (continued)

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. **IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.**

Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center right away.

Directions:

Adults:

1. Take 1 capsule every 4 to 6 hours while symptoms persist.
2. If pain or fever does not respond to 1 capsule, 2 capsules may be used but, do not exceed 6 capsules in 24 hours, unless directed by a doctor.
3. The smallest effective dose should be used.

Children: Do not give to children under 12 unless directed by a doctor.

Inactive Ingredients: FD&C Green No. 3, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol, sorbitan, and titanium oxide.

Store at room temperature 59-86 °F (15-30 °C). Avoid excessive heat 104 °F (40 °C).

If You Have Any Questions Or Comments
Please Call 1-800-XXX-XXXX

Dist. by: WHITEHALL-ROBINS HEALTHCARE
Madison, N.J. 07940
Made in U.S.A. © 1996 WHITEHALL-ROBINS HEALTHCARE
U.S. Patent No. 5,071,643
5,360,615

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APPROVED

FEB 5 1999

5 1999

NDA 20-402

Carton Back Panel--ADDENDUM

Active Ingredient (in each green oblong capsule)+.....**Purposes+**
Solubilized ibuprofen equal to 200 mg ibuprofen.....**Pain Reliever/**
(present as the free acid and potassium salt) **Fever Reducer**

Uses temporarily relieves minor aches and pains due to:

- the Common Cold, ▪ Toothache, ▪ Backache, ▪ Headache,
- Muscular Aches, ▪ Menstrual Cramps, ▪ Minor Pain of Arthritis
- temporarily reduces fever

Warnings+

Allergy Alert: ibuprofen may cause a severe allergic reaction which may include: ▪ hives ▪ facial swelling ▪ asthma (wheezing) ▪ shock

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do Not Use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- with any other pain reliever/fever reducer
- with any other product containing ibuprofen
- ~~▪ for more than 3 days for fever~~
- ~~▪ for more than 10 days for pain~~

Ask A Doctor Before Use If

- the painful area is red or swollen
- you take other drugs on a regular basis
- you are under a doctor's care for any continuing medical condition
- you have had problems or side effects with any pain reliever/fever reducer

Stop Using This Product And Ask A Doctor If

- an allergic reaction occurs. Seek medical help right away.
- ~~▪ symptoms continue or worsen~~
- stomach pain occurs with the use of this product
- any new or unexpected symptoms occur
- fever gets worse or last more than 3 days
- pain gets worse or last more than 10 days

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. It is especially important not use ibuprofen during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center right away.

NDA 20-402

Directions ■ Do not take more than directed

- adults: Take 1 capsule every 4 to 6 hours while symptoms occur
- If pain or fever does not respond to 1 capsule, 2 capsules may be used, but do not exceed 6 capsules in 24 hours unless directed by a doctor
- The smallest effective dose should be used
- children: Do not give to children under 12 unless directed by a doctor

Other information ■ Store at 20-25° C (68-77° F)

- Avoid excessive heat 40° C (above 104° F)

▲ Read all warnings and directions before use.

Inactive ingredients FD& C Green No. 3, Gelatin, Polyethylene Glycol, Potassium Hydroxide, Purified Water, Sorbitan, Sorbitol, Titanium Dioxide

© Questions? Call 1-800-88-ADVIL

Principal Display Panel - Carton

ADVIL

SOLUBILIZED IBUPROFEN CAPSULES, 200 mg

FPO Liqui-Gels®

20 Liqui-Gels Pain Reliever/Fever Reducer
(Liquid-filled capsule) advanced medicine for pain™

Drug Facts

Active ingredient (in each brown oval capsule)	Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen..... (present as the free acid and potassium salt)	Pain reliever

Use treats migraine

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- never had migraines diagnosed by a health professional
 - a headache that is different from your usual migraines
 - the worst headache of your life
 - fever and stiff neck
 - headaches beginning after or caused by head injury, exertion, coughing or bending
 - experienced your first headache after the age of 50
 - daily headaches
 - a migraine so severe as to require bed rest
 - problems or serious side effects from taking pain relievers or fever reducers
 - stomach pain
-

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any continuing medical condition
 - taking other drugs on a regular basis
 - taking another product containing ibuprofen, or any other pain reliever/fever reducer
-

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
 - migraine headache pain is not relieved or gets worse after first dose
 - stomach pain occurs with the use of this product
 - new or unexpected symptoms occur
-

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

adults:	<ul style="list-style-type: none">• take 2 capsules with a glass of water• if symptoms persist or worsen, ask your doctor• do not take more than 2 capsules in 24 hours, unless directed by a doctor
under 18 years of age:	<ul style="list-style-type: none">• ask a doctor

Other information

- read all directions and warnings before use. Keep carton.
- store at 20 - 25°C (68 - 77°F)
- avoid excessive heat 40°C (above 104°F)

Inactive ingredients black iron oxide, D&C yellow no. 10, FD&C green no. 3, FD&C red no. 40, gelatin, lecithin, light mineral oil, pharmaceutical glaze, polyethylene glycol, potassium hydroxide, purified water, simethicone, sorbitan, sorbitol

Questions? Call 1-800-88-ADVIL

Do not use if seal under bottle cap imprinted with "Sealed for Your Protection" is broken or missing

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