

REVIEWED LABELING

Advil Liqui-Gels: Carton

Summary of proposed changes to **Warnings** section of the Drug Facts panel with changes highlighted in red.

New/Revised Warnings	Previous Warnings
<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. 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.</p>	<p>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.</p>
<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>
<p>Ask a doctor before use if you have ■ problems or serious side effects from taking pain relievers or fever reducers ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain ■ ulcers ■ bleeding problems ■ high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age</p>	<p>Ask a doctor before use if you have had problems or side effects with any pain reliever/fever reducer</p>
<p>Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious medical condition ■ taking any other product that contains ibuprofen or any other pain reliever/fever reducer ■ taking a prescription drug for anticoagulation (blood thinning) ■ taking any other drug</p>	<p>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 any other product containing ibuprofen, or any other pain reliever/fever reducer</p>
<p>When using this product take with food or milk if stomach upset occurs</p>	
<p>Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ pain get worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear</p>	<p>Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ fever gets worse or lasts more than 3 days ■ pain gets worse or lasts more than 10 days ■ stomach pain occurs with the use of this product ■ the painful area is red or swollen ■ any new or unexpected symptoms occur</p>

Advil Migraine: Carton

Summary of proposed changes to *Warnings* section of the Drug Facts panel with changes highlighted in red.

New/Revised Warnings	Previous Warnings
<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. 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.</p>	<p>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.</p>
<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>
<p>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, exertions, 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 problems that last or come back, such as heartburn, upset stomach, or pain ■ ulcers ■ bleeding problems ■ high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age</p>	<p>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, exertions, 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</p>
<p>Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious medical condition ■ taking any other product that contains ibuprofen or any other pain reliever/fever reducer ■ taking a prescription drug for anticoagulation (blood thinning) ■ taking any other drug</p>	<p>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 any other product containing ibuprofen, or any other pain reliever/fever reducer</p>
<p>When using this product take with food or milk if stomach upset occurs</p>	
<p>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 or upset occurs with use of this product ■ any new symptoms appear</p>	<p>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</p>

Advil Liqui-Gels: Bottle

(A) Last approved label and (B) proposed label

A

Warnings

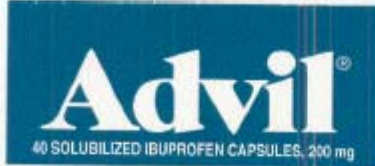
Allergy alert: ibuprofen may cause a severe allergic reaction which may include:

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

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

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.

Dist. by
Whitehall-Robins Healthcare
Madison, NJ 07940 Made in USA



Active ingredient
(in each green oblong capsule)
Solubilized ibuprofen equal to 200 mg ibuprofen, Pain reliever/
(present as the free acid and potassium salt) fever reducer

Purposes

Uses: temporarily relieves minor aches and pains due to:

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

Temporarily reduces fever



IF FOIL SEAL UNDER BOTTLE CAP IMPRINTED "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING, DO NOT USE.

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

Store at 20-25°C (68-77°F)

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

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B

Warnings

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

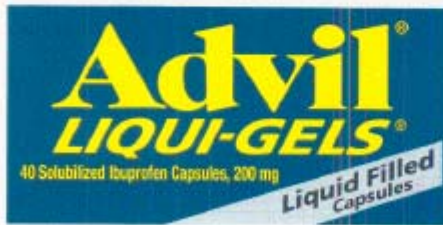
- hives ■ facial swelling
- asthma (wheezing) ■ shock

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

Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.

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.



Active ingredient (in each capsule)
Solubilized ibuprofen equal to 200 mg ibuprofen, Pain reliever/
(present as the free acid and potassium salt) fever reducer

Purposes

Uses: temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

SEE CARTON FOR COMPLETE INFORMATION

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

Directions

- do not take more than directed
 - 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
 - the smallest effective dose should be used
 - children under 12 years: ask a doctor
- Store at 20-25°C (68-77°F). Avoid excessive heat 40°C (above 104°F).

U0169-30-D1



Liqui-Gels® is a trademark of R.P. Scherer Corp.
Dist. by Wyeth Consumer Healthcare
Madison, NJ 07940 Made in U.S.A.
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U.S. Patent Nos. 5,071,643 and 5,360,615