IBUPROFEN MINIS- ibuprofen capsule, liquid filled Harris Teeter, LLC

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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - slurred speech
 - trouble breathing
 - leg swelling
 - 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 right away (1-800-222-1222).

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). Protect from light.
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

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

Questions or comments?

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

Principal Display Panel

†Compare to he active ingredient in Advil® Liqui-Gels® minis

Ibuprofen

Capsules, 200 mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

minis

Liquid-filled capsules

†This product is not manufactured or distributed by GlaxoSmithKline Consumer

Healthcare Holdings (US) LLC, distributor of Advil® Liqui-Gels® minis.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

HARRIS TEETER, LLC

MATTHEWS, NC 28105

harristeeter.com

Product Label

	Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or tater in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unbom child or complications during delivery. Reep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Miler and trace of the children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Directions D				
This product is not manufactured or distributed by GlazoSmithKline Consumer Healthcare Holdings (IKS) LLC, distributor of Anvite Liqui-Gels [®] minits. PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC MATTHEWS, NC 28105 - 1-800-432-5111 or harristeter.com 1-800-432-5111 or harristeter.com 1-800-432-511 or harristeter.com 1-800-432-510 or harristet	Drug Facts (continued) Do not use If you have even had an allergic reaction to any other pain relevent reducer If you have even had an allergic reaction to any other pain relevent reducer If you have problems or serious side effects from taking pain relevents or serious side effects from taking pain relevents or serious side effects from taking pain relevent explores You have a history of stomach problems, such as heartburn vou have a history of stomach problems, such as heartburn vou have a history of stomach problems, such as heartburn vou have a history of stomach problems, such as heartburn vou have a history of stomach problems, such as a concernation a doctor's care for any sections condition. You have a bisch problem or set lay ou are burber are taking a dure to a doctor's care for any sections condition. You are a doctor or pharmacist before use if you are docreasen this benefit of react. Hen using this product, take with food or milk if stomach upset cocurs. You experience any of the following signs of stomach bleeding: teachers and ask a doctor if Group use and ask a doctor if When using this product, take with food or milk if stomach upset cocurs. Tealing any other drug When using this product, take with food or milk if stomach upset cocurs. Tealing any other drug Tealing any other drug Tealing any other drug To u experience and of the collowing signs of stomach theeding: tealart				
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	Capsules, 200 mg PAIN RELIEVER / FEVER REDUCER (NSAID) minis B0 Liquid-filled capsules				



IBUPROFE	N MINIS	5							
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Product Info	ormation								
Product Type		HUMAN OTC DRUG	G Iter	Item Code (Source)			DC:69256-843		
Route of Admi	nistration	ORAL							
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Active Ingredient/Active Moiety									
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							-		
Inactive Ing	redients								
	Ingredient Name						Strength		
FD&C GREEN NO). 3 (UNII: 3P	30NR601S)							
GELATIN (UNII: 2G86QN327L)									
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)									
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)									
WATER (UNII: 059	9QF0KO0R)								
SORBITOL (UNII:									
SORBITAN (UNII: 6092ICV9RU)									
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1	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product								
Marketing	Inform	nation							
Marketing Category	Арр	lication Number or Citation	Monograp	h №	larketing Start Date	Mar	keting End Date		

ANDA

03/27/2020

Labeler - Harris Teeter, LLC (048463103)

Revised: 2/2023

Harris Teeter, LLC