

PROPRINAL- ibuprofen capsules 200 mg capsule, liquid filled
HART Health

PROPRINAL

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
- backache
- minor arthritis pain
- the common cold
- toothache
- 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
- blisters
- shock
- facial swelling
- asthma (wheezing)
- rash
- skin reddening

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 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, 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
- take aspirin for heart attack or stroke (ibuprofen may decrease this benefit of aspirin)
- take any other drug

When using this product take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better
- new symptoms occur
- redness or swelling is present
- you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of the body, slurred speech, or leg swelling

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 take more than 6 capsules in 24 hours, unless directed by a doctor

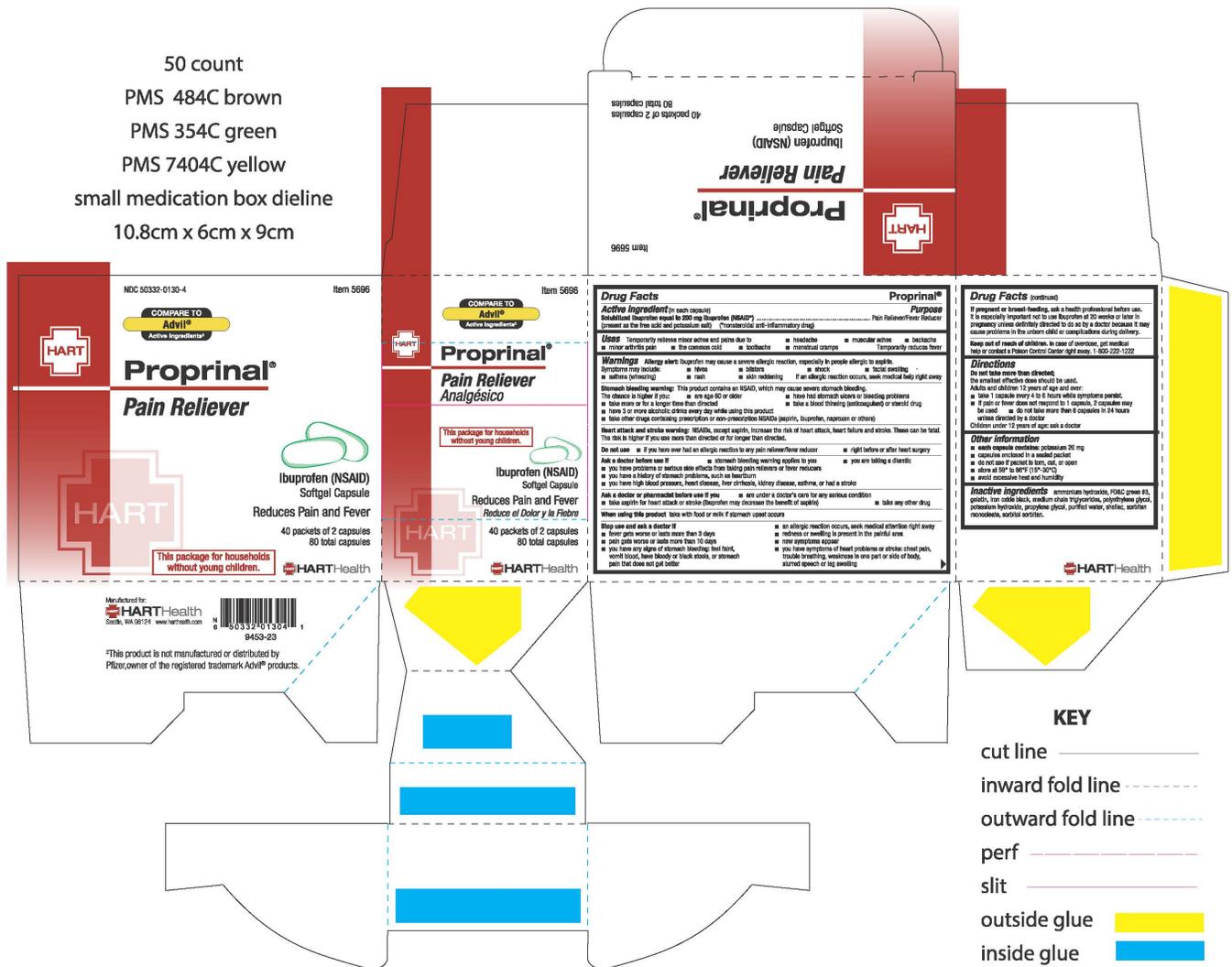
children under 12 years of age : ask a doctor

OTHER INFORMATION

Other information

- each capsule contains: potassium 20 mg
- caplets enclosed in a sealed packet
- do not use if packet is torn, cut or open
- store at 59° to 86°F (15°-30°C)
- avoid excessive heat and humidity

Inactive ingredients Ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitan monooleate, sorbitol sorbitan



PROPRINAL

ibuprofen capsules 200 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0130
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
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
AMMONIA (UNII: 5138Q19F1X)	
GELATIN (UNII: 2G86QN327L)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0130-3	20 in 1 BAG	01/11/2017	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0130-4	40 in 1 BOX	01/11/2017	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0130-7	100 in 1 BOX	01/11/2017	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0130-8	200 in 1 BOX	01/11/2017	
		2 in 1 PACKET; Type 0: Not a Combination		

4		2 in 1 PACKET; Type 0: Not a Combination Product	
5	NDC:50332-0130-1	300 in 1 BOX	01/11/2017
5		2 in 1 PACKET; Type 0: Not a Combination Product	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	01/11/2017	

Labeler - HART Health (069560969)

Revised: 8/2023

HART Health