ADVIL MIGRAINE- ibuprofen capsule, liquid filled
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each brown oval capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Use

- treats migraine

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.

Medication overuse headache warning:

Headaches may worsen if this product is used for 10 or more days per month.

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

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you have experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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
  - trouble breathing

    - weakness in one part or side of body
    - slurred speech
    - leg swelling
- migraine headache pain is not relieved or gets worse after the first dose
- 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.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults: 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: ask a doctor

Other information

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

Inactive ingredients

D&C yellow no. 10, FD&C green no. 3, FD&C red no. 40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

Questions or Comments?

Call toll-free **1-800-88-ADVIL**

Additional Information

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

For most recent product information, visit **www.Advil.com**

PRINCIPAL DISPLAY PANEL

Advil
MIGRAINE

Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever **(NSAID)**

20
Liquid Filled
Capsules

000068423 Front Carton

ADVIL MIGRAINE

ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0168
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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	brown (translucent brown)	**Score**	no score
Shape	OVAL (soft gelatin capsule)	**Size**	17mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0168-20	1 in 1 CARTON	03/16/2000	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0168-30	1 in 1 CARTON	03/16/2000	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0168-40	1 in 1 CARTON	03/16/2000	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020402	03/16/2000	

Labeler - Haleon US Holdings LLC (079944263)