

ADVIL PM- diphenhydramine citrate, ibuprofen tablet, coated
Navajo Manufacturing Company Inc.

Advil PM

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine citrate 38 mg

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Nighttime sleep-aid

Pain reliever

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

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 • rash • skin reddening • 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

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, or asthma
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

you are

- taking sedatives or tranquilizers, or any other sleep-aid
- under a doctor's care for any continuing medical illness
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- 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 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 the 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
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets in 24 hours

Other information

- 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)

Inactive ingredients

calcium stearate, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call toll free 1-800-88-ADVIL

Package Labeling:



ADVIL PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-147(NDC:0573-0164)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE CITRATE
IBUPROFEN (UNII: WK2XYH10QM) (IBUPROFEN - UNII:WK2XYH10QM)		200 mg

Inactive Ingredients	
Ingredient Name	
CALCIUM STEARATE (UNII: 776 XM7047L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM O XIDE (UNII: LM26O6933)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	Advil;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-147-01	1 in 1 CARTON	09/16/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-147-02	2 in 1 CARTON	09/16/2016	
2		4 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021394	09/16/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-147) , repack(67751-147)