

HANDY SOLUTIONS IBUPROFEN- ibuprofen tablet, coated
Navajo Manufacturing Company Inc.

Handy Solutions Ibuprofen

Drug Facts

Active ingredients (in each caplet)

Ibuprofen 200 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches, pains and fever associated with:

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

Temporarily reduces fever.

Warnings

Allergy Alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

• hives • skin reddening • asthma (wheezing) • facial swelling • rash • shock • 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 or fever reducer
- right before or after heart surgery

Ask a doctor before use if you have

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product

- 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new or unexpected symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than directed
- the smallest effective dose should be used

Adults and children 12 years of age and older: Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used. Do not exceed 6 tablets in 24 hours, unless directed by a doctor.

Children under 12 years or age: Do not give to children under 12 years of age.

Other information

- Tamper evident. Do not use if packet is torn, cut or opened.
- store at controlled room temperatures 20° to 25°C (68° to 77°F)
- Avoid excessive heat above 40°C (104°F)
- Read all product information before using

Inactive ingredients

carnauba wax*, corn starch, hypromellose, iron oxide red, lactose monohydrate*, magnesium stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, povidone K30*, silicon dioxide, sodium starch glycolate, stearic acid, titanium dioxide, triacetin*

*may contain

Questions or comments?

1-800-525-5097

Package Labeling:



HANDY SOLUTIONS IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-164(NDC:47682-600)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN
		200 mg
Inactive Ingredients		
Ingredient Name		Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)		
STARCH, CORN (UNII: O8232NY3SJ)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYDEXTROSE (UNII: VH2XOU12IE)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE K30 (UNII: U725QWY32X)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
TRIACETIN (UNII: XHX3C3X673)		

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-164-01	1 in 1 CARTON	09/22/2016	
1		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
ANDA	ANDA075010	09/22/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-164)

Revised: 11/2019

Navajo Manufacturing Company Inc.