ACETAMINOPHEN AND IBUPROFEN (NSAID)- acetaminophen and ibuprofen (nsaid) tablet
Wal-Mart Stores Inc.

Dual action
Pain Reliever
Acetaminophen 250 mg and Ibuprofen (NSAID) 125 mg Tablets
Pain Reliever
CONTAINS 2 MEDICINES
Acetaminophen + Ibuprofen

Active ingredients (in each caplet)

Acetaminophen 250mg

Ibuprofen 125mg (NSAID**)
**nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Uses

■ temporarily relievesminor aches and pains due to:
■ headache ■ toothache ■ backache
■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damagemay occur if you take:
■ with other drugs containing acetaminophen
■ more than 6 caplets in 24 hours,which is themaximumdaily amount for this product
■ 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert:

may cause severe skin reactions.Symptomsmay include:
■ skin reddening ■ blisters ■ rash
If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert:

ibuprofenmay cause a severe allergic reaction, especially in people allergic to aspirin.
Symptomsmay include:

■ hives ■ facial swelling ■ asthma (wheezing)
■ shock ■ skin reddening ■ rash ■ blisters
If an allergic reaction occurs, stop use and seekmedical help right away.

NSAID stomach bleedingwarning:

This product contains an NSAID, whichmay 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 ormore alcoholic drinks every day while using this product

■ take more or for a longer time than directed

Heart attack and strokewarning:

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

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
■ if you have ever had an allergic reaction to acetaminophen or any other pain reliever
■ right before or after heart surgery

Ask a doctor before use if

■ you have liver disease
■ stomach bleeding warning applies to you
■ you have problems or serious side effects fromtaking pain relievers
■ 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 ibuprofenmay decrease this benefit of aspirin
■ taking any other drug

When using this product

■ Take with food ormilk 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
■ pain gets worse or lastsmore than 10 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 itmay cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, getmedical help or contact a Poison Control Center right away. Promptmedical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ **do not takemore than directed**

adults and children 12 years and over

■ **take 2 caplets every 8 hours** while symptoms persist

children under 12 years

■ ask a doctor

■ do not takemore than 6 caplets in 24 hours, unless directed by a doctor

Other information

■ read all warnings and directions before use. Keep carton.
■ store at 20 to 25°C (68 to 77°F)
■ avoid excessive heat above 40°C (104°F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, crospovidone, ferric oxide red, ferric oxide yellow, hypromellose, magnesium stearate, microcrystalline

cellulose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, sodiumlauryl sulfate, stearic acid and titaniumdioxide.

Questions or comments?

1-888-287-1915

Principal display panel

ACETAMINOPHEN AND IBUPROFEN (NSAID)

acetaminophen and ibuprofen (nsaid) tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79903-931
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	125 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	yellow (Light yellow to yellow colored)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	G;131
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-931-44	144 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216592	07/18/2023	

Labeler - Wal-Mart Stores Inc. (051957769)

Revised: 7/2023 Wal-Mart Stores Inc.