

ACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet WALGREENS

Dual Pain Reliever

Acetaminophen 250mg & Ibuprofen (NSAID) 125mg Tablets/ Pain Reliever

Acetaminophen + Ibuprofen

Contains 2 Medicines

Active Ingredients (in each caplet)

Acetaminophen 250mg

Ibuprofen 125mg (NSAID)

Purposes

Pain Reliever

Pain reliever

Uses

■ temporarily relieves minor 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 damage may occur if you take:

■ with other drugs containing acetaminophen

■ more than 6 caplets in 24 hours, which is the maximum daily amount for this product

■ 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert

may cause severe skin reactions. Symptoms may include:

■ skin reddening ■ blisters ■ rash

If skin reaction occurs, stop use and seek medical help right away.

NSAID 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

NSAID 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

- 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 from taking 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 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
- pain gets worse or lasts more 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 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ do not take more 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 take more 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, sodium lauryl sulfate, stearic acid and titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

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144 CAPLETS*
(*capsule-shaped tablets)

WALGREENS
Choose to be active by choice.
Infect • Effect • Active

Dual Pain Reliever
ACETAMINOPHEN 250 mg & IBUPROFEN (NSAID) 125 mg TABLETS / PAIN RELIEVER

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ACETAMINOPHEN 250 mg & IBUPROFEN (NSAID) 125 mg TABLETS / PAIN RELIEVER

CONTRAINDICATIONS • Acetaminophen + Ibuprofen • DUAL ACTION

ACTIVE INGREDIENTS
Acetaminophen 250 mg
Ibuprofen (NSAID) 125 mg

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, sodium lauryl sulfate, stearic acid and titanium dioxide

HOW TO USE
Take 1 or 2 caplets every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours. Do not take for more than 10 days unless directed by a doctor.

WARNING
Do not take if you are allergic to acetaminophen or ibuprofen. Do not take if you are taking other pain relievers. Do not take if you are pregnant or breastfeeding. Do not take if you have liver or kidney disease. Do not take if you have a history of stomach ulcers or bleeding. Do not take if you have a history of heart disease or high blood pressure. Do not take if you have a history of asthma. Do not take if you have a history of alcoholism. Do not take if you are taking other medications.

ADVERSE REACTIONS
Common side effects include drowsiness, dizziness, headache, and upset stomach. Serious side effects include liver damage, kidney damage, stomach ulcers, and heart problems.

DRUG INTERACTIONS
Do not take with alcohol. Do not take with other pain relievers. Do not take with blood thinners. Do not take with certain antibiotics. Do not take with certain antifungal medications. Do not take with certain antidepressants. Do not take with certain antipsychotics. Do not take with certain anti-seizure medications. Do not take with certain anti-viral medications. Do not take with certain anti-cancer medications. Do not take with certain anti-diabetic medications. Do not take with certain anti-hypertensive medications. Do not take with certain anti-arrhythmic medications. Do not take with certain anti-inflammatory medications. Do not take with certain anti-parasitic medications. Do not take with certain anti-fungal medications. Do not take with certain anti-viral medications. Do not take with certain anti-cancer medications. Do not take with certain anti-diabetic medications. Do not take with certain anti-hypertensive medications. Do not take with certain anti-arrhythmic medications. Do not take with certain anti-inflammatory medications. Do not take with certain anti-parasitic medications.

USE IN PREGNANT AND BREASTFEEDING WOMEN
Do not take if you are pregnant or breastfeeding.

USE IN CHILDREN
Do not take in children under 18 years of age.

USE IN ELDERLY
Do not take in elderly patients without medical supervision.

USE IN PATIENTS WITH LIVER OR KIDNEY DISEASE
Do not take in patients with liver or kidney disease.

USE IN PATIENTS WITH STOMACH ULCERS OR BLEEDING
Do not take in patients with stomach ulcers or bleeding.

USE IN PATIENTS WITH HEART DISEASE OR HIGH BLOOD PRESSURE
Do not take in patients with heart disease or high blood pressure.

USE IN PATIENTS WITH ASTHMA
Do not take in patients with asthma.

USE IN PATIENTS WITH ALCOHOLISM
Do not take in patients with alcoholism.

USE IN PATIENTS TAKING OTHER MEDICATIONS
Do not take if you are taking other medications.

HOW TO STORE
Store at room temperature (20° to 25°C). Excursions permitted to 15° to 30°C. Do not store in the bathroom. Do not store in the kitchen. Do not store in the car. Do not store in the trunk of the car. Do not store in the garage. Do not store in the basement. Do not store in the attic. Do not store in the crawlspace. Do not store in the crawlspace. Do not store in the crawlspace.

HOW TO OBTAIN
Available without a prescription.

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ACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9131
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	125 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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:0363-9131-16	216 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
2	NDC:0363-9131-44	144 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216592	07/19/2023	

Labeler - WALGREENS (008965063)