

AACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet GRANULES USA, INC.

Dual Action

Pain Reliever

Contains 2 Medicines

Acetaminophen and Ibuprofen (NSAID) Tablets 250mg/125mg

Active ingredients (in each caplet)

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID**)

**nonsteroidal anti-inflammatory drug

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.

Principal display panel



NDC 69848-588-72

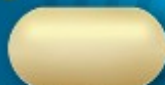
***Compare to the active ingredients of Advil® Dual Action**

Contains 2 Medicines

Acetaminophen and Ibuprofen (NSAID)

Tablets 250 mg/125 mg

- Dual Action
- Pain Reliever



72 Caplets[†] Actual Size
(capsule-shaped tablets)

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN; CAN CAUSE LIVER DAMAGE

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg _____ Pain reliever

Ibuprofen 125 mg (NSAID**) _____ Pain reliever

**nonsteroidal anti-inflammatory drug

Uses

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

Warnings

Drug Facts (continued)

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take:

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- 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

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- rash
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LOT EXP

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PEEL HERE

Distributed by: Granules Consumer Health (A Division of Granules USA, Inc.)
35 Waterview Blvd., 3rd Floor, 2000000867 703000041111 MADE IN INDIA
Parsippany, NJ 07054

INSIDE

Drug Facts (continued)

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Drug Facts (continued)

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

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Drug Facts (continued)

- you have a history of stomach problems such as heartburn
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Ask a doctor or pharmacist before use if you are

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BASE

Drug Facts (continued)

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Questions or comments?

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IMPORTANT: READ THE DIRECTIONS AND WARNINGS BEFORE USE

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AACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet

Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:69848-588
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: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			IBUPROFEN	125 mg
Inactive Ingredients				
Ingredient Name				Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POVIDONE K30 (UNII: U725QWY32X)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)				
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CROSPVIDONE (UNII: 2S7830E561)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
Product Characteristics				
Color	yellow (Light yellow to yellow colored)		Score	no score
Shape	CAPSULE (capsule shaped, biconvex)		Size	14mm
Flavor			Imprint Code	G131
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-588-72	72 in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2024	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA216592	12/10/2024	
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Labeler - GRANULES USA, INC. (137098864)

Revised: 12/2024

GRANULES USA, INC.