ACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet Granules Pharmaceuticals Inc.

Acetaminophen and Ibuprofen

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:
- o headache
- o toothache
- o backache
- o menstrual cramps
- o muscular aches
- o minor pain of arthritis

Warnings

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 - 18's Container Label

NDC 70010-131-26

[†]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

8

Hour

Relief

18 Caplets*

(*capsule-shaped tablets)

NDC 70010-131-26 ¹ Compare to the Active Ingredients of Advil [®] Dual Action Contains 2 Medicines		Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage. READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION	Drug Facts (continued) Warnings Acetaminophen liver damage warning:	BACK OF LABEL) Rev. 06/2025	Free
Acetaminophen and Ibuprofen (NSAID) Tablets 250 mg/125 mg	le cap imprinted with " missing.	Acetaminophen 250 mgPain reliever buprofen 125 mg (NSAID**) Pain reliever	Accuminophen anergy dere may oddoe severe sharredouoris.	(CONTINUED ON s Inc., Chantily, VA 20151	
Dual Action 8 Pain Reliever Hour Relief 18 Caplets* (*capsule-shaped tablets)	Do Not Use if seal under both PROTECTION" is broken or	Uses temporarily relieves minor aches and pains due to: headache toothache backache menstrual cramps muscular aches minor pain of arthritis	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:	Manufactured by: Granules Pharmaceuticals Inc	PHL HERE

Drug Facts (continued)	Drug Facts (continued)	Drug Facts (continued)
■ hives ■ facial swelling ■ asthma (wheezing)	Heart attack and stroke warning:	you have problems or serious side effects from taking
■ shock ■ skin reddening ■ rash ■ blisters	NSAIDs, except aspirin, increase the risk of heart attack,	pain relievers
If an allergic reaction occurs, stop use and seek medical		you have a history of stomach problems such as heartburn
help right away.	if you use more than directed or for longer than directed.	■ you have high blood pressure, heart disease, liver cirrhosis,
NSAID stomach bleeding warning:	Do not use	kidney disease, asthma, or had a stroke
This product contains an NSAID, which may cause severe	with any other drug containing acetaminophen	you are taking a diuretic
stomach bleeding. The chance is higher if you:	(prescription or nonprescription). If you are not sure	Ask a doctor or pharmacist before use if you are
are age 60 or older	whether a drug contains acetaminophen, ask a doctor	under a doctor's care for any serious condition
have had stomach ulcers or bleeding problems	or pharmacist	taking aspirin for heart attack or stroke, because ibuprofen
take a blood thinning (anticoagulant) or steroid drug	if you have ever had an allergic reaction to acetaminophen	may decrease this benefit of aspirin
take other drugs containing prescription or nonprescription		taking any other drug
NSAIDs [aspirin, ibuprofen, naproxen, or others]	■ right before or after heart surgery	When using this product
have 3 or more alcoholic drinks every day while using this	Ask a doctor before use if	Take with food or milk if stomach upset occurs
product	vou have liver disease	Stop use and ask a doctor if
take more or for a longer time than directed	stomach bleeding warning applies to you	you experience any of the following signs of stomach bleeding:

Drug Facts (continued)	Drug Facts (continued)		Drug Facts (continued)	
 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: 	medical help or conta Prompt medical atten	i children. In case of overdose, get ct a Poison Control Center right away. tion is critical for adults as well as for out patients any given or cumptance	 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) 	
chest pain trouble breathing	children even if you do not notice any signs or symptoms. <i>Directions</i> do not take more than directed		Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, crospovidone, ferric oxide r ferric oxide yellow, hypromellose, magnesium stearate,	
pain gets worse or lasts more than 10 days redness or swelling is present in the painful area	adults and children 12 years and over	take 2 caplets every 8 hours while symptoms persist	microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, sodium lauryl sulfate, stearic acid and titanium dioxide.	
	children under 12 years	∎ ask a doctor	Questions or comments?	
20 weeks or later in pregnancy unless definitely directed to do	 do not take more than 6 caplets in 24 hours, unless directed by a doctor Other information 		call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST. †All trademarks are property of their respective owners	
so by a doctor because it may cause problems in the unborn child or complications during delivery.			This product is not affiliated with the makers/owners Advil [®] Dual Action	

NDC 70010-131-26

 $^{\dagger}\text{Compare}$ to the Active Ingredients of Advil $^{\$}$ Dual Action

Contains 2 Medicines

Acetaminophen and Ibuprofen (NSAID) Tablets

250 mg/125 mg

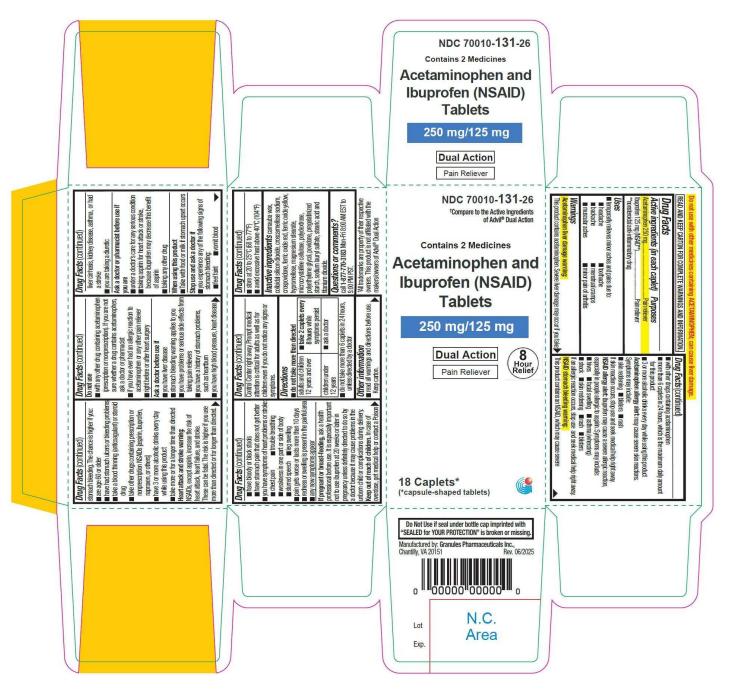
Dual Action 8

Pain Reliever Hour

Relief

18 Caplets*

(*capsule-shaped tablets)



ACETAMINOPHEN AI	ND IBUPROFEN					
acetaminophen and ibuprofe	n tablet					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sou	urce)	NDC:700	10-131	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingr	edient Name		Basis of St	rength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 250 mg						
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM) IBUPROFEN 125 mg						

	Strength					
Ingredient Name Strength HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6) Strength						
HYPROMELL	.OSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)					
MAGNESIUM	I STEARATE (UNII: 70097M6I30)					
CELLULOSE,	, MICROCRYSTALLINE (UNII: OP1R32D61U)					
POLYDEXTR	OSE (UNII: VH2XOU12IE)					
POLYETHYL	ENE GLYCOL 400 (UNII: B697894SGQ)					
POVIDONE K	(30 (UNII: U725QWY32X)					
POVIDONE K	(90 (UNII: RDH86HJV5Z)					
CARNAUBA	WAX (UNII: R12CBM0EIZ)					
SILICON DIO	DXIDE (UNII: ETJ7Z6XBU4)					
CROSCARME	ELLOSE SODIUM (UNII: M280L1HH48)					
CROSPOVID	ONE (UNII: 68401960MK)					
FERRIC OXI	DE RED (UNII: 1K09F3G675)					
FERRIC OXI	DE YELLOW (UNII: EX438O2MRT)					
	OSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)					
	PRN (UNII: 08232NY3SJ)					
	JRYL SULFATE (UNII: 368GB5141J)					
	ID (UNII: 4ELV7Z65AP)					
TITANIUM D	IOXIDE (UNII: 15FIX9V2JP)					
Product C	Characteristics					
Color yellow (Light yellow to yellow colored) Score no score						
Shape						
Flavor		Imprint Code	G;131			
Contains						

	Fackaging						
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:70010-131- 26	1 in 1 CARTON	07/24/2023				
1		18 in 1 BOTTLE; Type 0: Not a Combination Product					
2	NDC:70010-131- 31	288 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2023				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216592	07/24/2023	
ANDA	ANDA216592	07/24/2023	

Establishment							
Name Ad			ess	ID/FEI	Business Operations		
Granules Pharmaceuticals Inc.				079825711	analysis(70010-131) , manufacture(70010-131)		
Establishment							
Name	Address	ID/FEI	Business Operations				
Granules India Limited		918609236	manufacture(70010-131) , pack(70010-131) , label(70010-131) , analysis(70010-131)				

Revised: 6/2025

Granules Pharmaceuticals Inc.