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

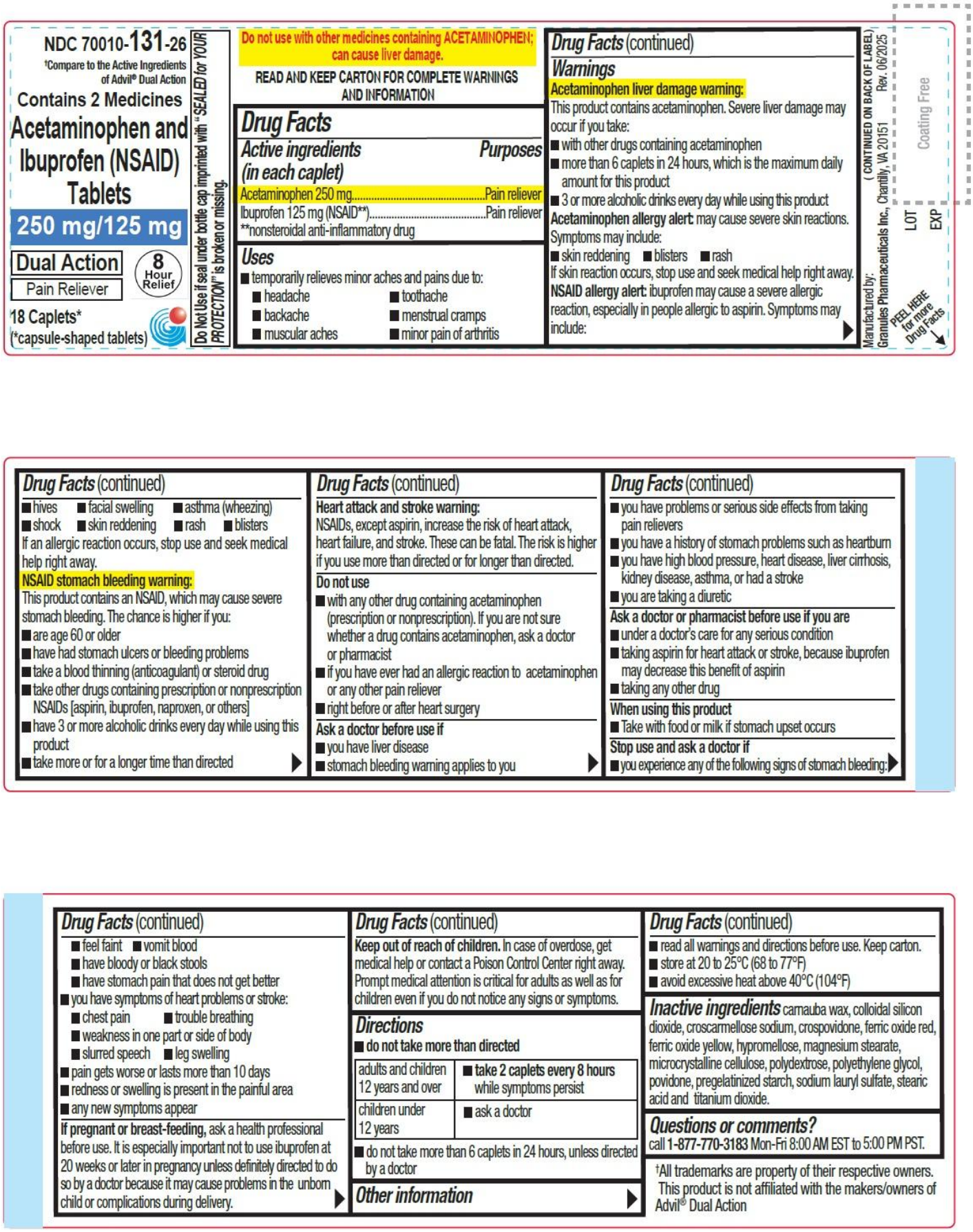
8

Hour

Relief

18 Caplets*

(*capsule-shaped tablets)



PRINCIPAL DISPLAY PANEL - 18's Container Carton Label

NDC 70010-131-26

†Compare to the Active Ingredients of Advil ® Dual Action

Contains 2 Medicines

Acetaminophen and Ibuprofen (NSAID) Tablets

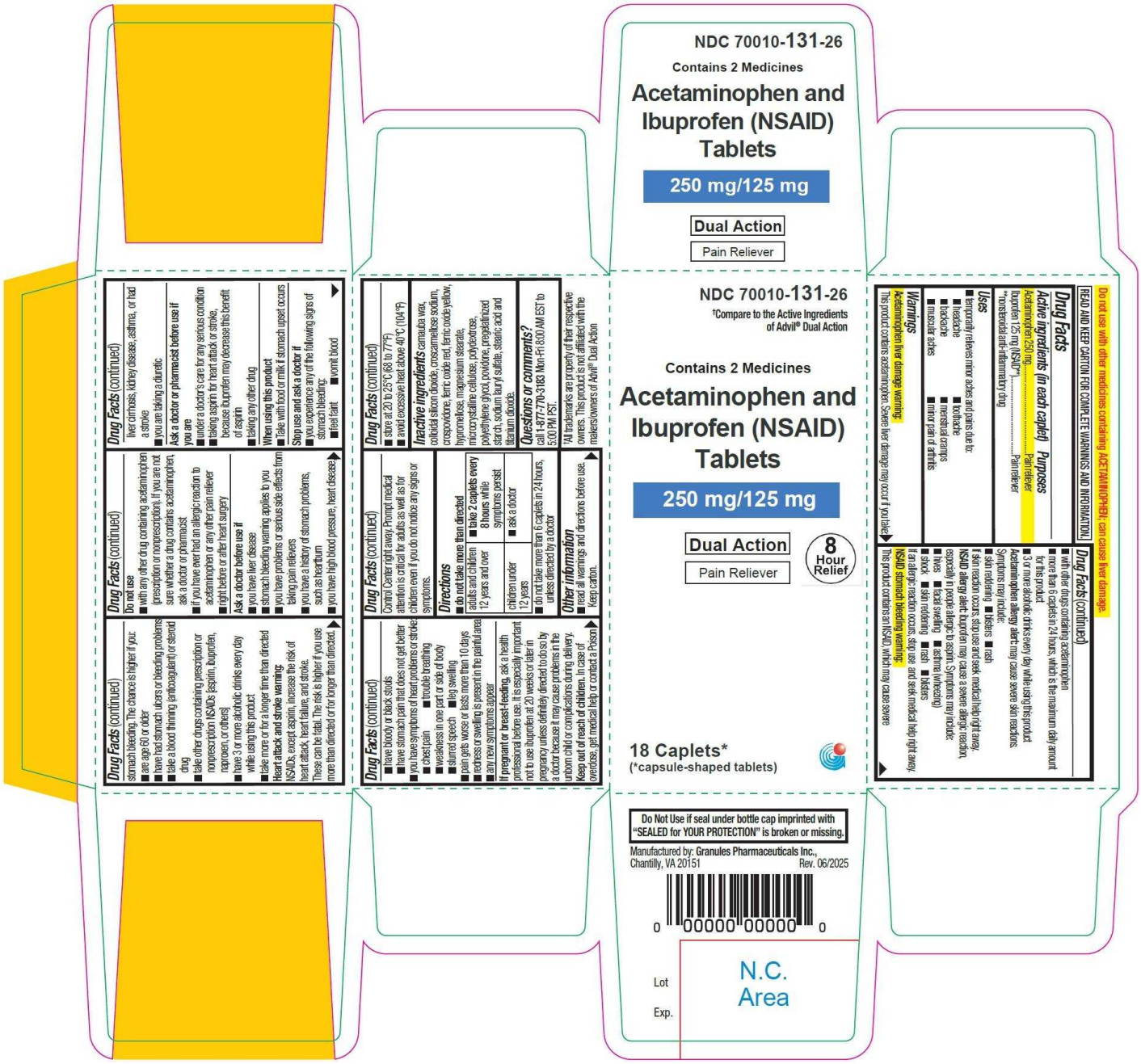
250 mg/125 mg

Dual Action 8

Pain Reliever Hour

Relief

18 Caplets*
(*capsule-shaped tablets)



ACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70010-131
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
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item 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	

Labeler - Granules Pharmaceuticals Inc. (079825711)

Establishment

Name	Address	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)