

**ACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet, film coated**  
**AMERISOURCE BERGEN**

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***Good Neighbor Pharmacy Acetaminophen and Ibuprofen Tablets***

***Active ingredients (in each caplet)***

Acetaminophen, USP 250 mg

Ibuprofen, USP 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

***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

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adults and children 12 years and over	■ <b>take 2 caplets every 8 hours</b> while symptoms persist
children under 12 years	■ ask a doctor

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

## Other information

- each caplet contains: **sodium 3 mg**
- read all warnings and directions before use. Keep carton.
- store at 20°C to 25°C (68°F 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, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, sodium lauryl sulphate, stearic acid, titanium dioxide

## Questions or comments?

call toll-free **1-888-235-2466**

\*\*\*This product is not manufactured or distributed by the owners of Advil® Dual Action with Acetaminophen.

**DO NOT USE IF TAMPER-EVIDENT 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.**

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

Distributed by:

**AmerisourceBergen**

1 West First Ave

Conshohocken, PA 19428

Questions or Concerns?

[www.mygnp.com](http://www.mygnp.com)

**ABC#: 10274882**

R0123

L0000668

Lot No.:

Exp. Date:

**PRINCIPAL DISPLAY PANEL**

Compare to the active ingredient in Advil® Dual Action with Acetaminophen

NDC 46122-742-68

Good

Neighbor

Pharmacy

Acetaminophen and Ibuprofen (NSAID)

Tablets, 250 mg/125 mg

DUAL ACTION PAIN RELIEVER

CONTAINS 2 MEDICINES

Acetaminophen + Ibuprofen

36 Caplets\*\*

\*\*capsule-shaped tablets

Peelback label

# Top Ply

<b>Drug Facts</b> <b>Active ingredients</b> <b>Purpose(s)</b> Acetaminophen USP 325 mg, Pain reliever Ibuprofen USP 100 mg, Pain reliever *Nonsteroidal anti-inflammatory drug		<b>Warnings</b> Acetaminophen liver damage warning: This product contains acetaminophen. Severe liver damage may occur if you take: • with other drugs containing acetaminophen • more than 6 capsules in 24 hours, which is the maximum daily amount for this product • 3 or more alcohol drinks every day while using this product
<b>Directions</b> For temporary relief of minor aches and pains due to: • headache • toothache • backache • menstrual cramps • muscular aches • minor pain of arthritis		
<b>Drug Facts (continued)</b> Acetaminophen may cause the following side effects. If you experience any of the following, stop use and seek medical help right away. • Allergic reactions: Acetaminophen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • hives • difficulty breathing • swelling of the face, lips, tongue, or throat • dizziness • rash • If an allergic reaction occurs, stop use and seek medical help right away. • Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: • are age 65 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug		

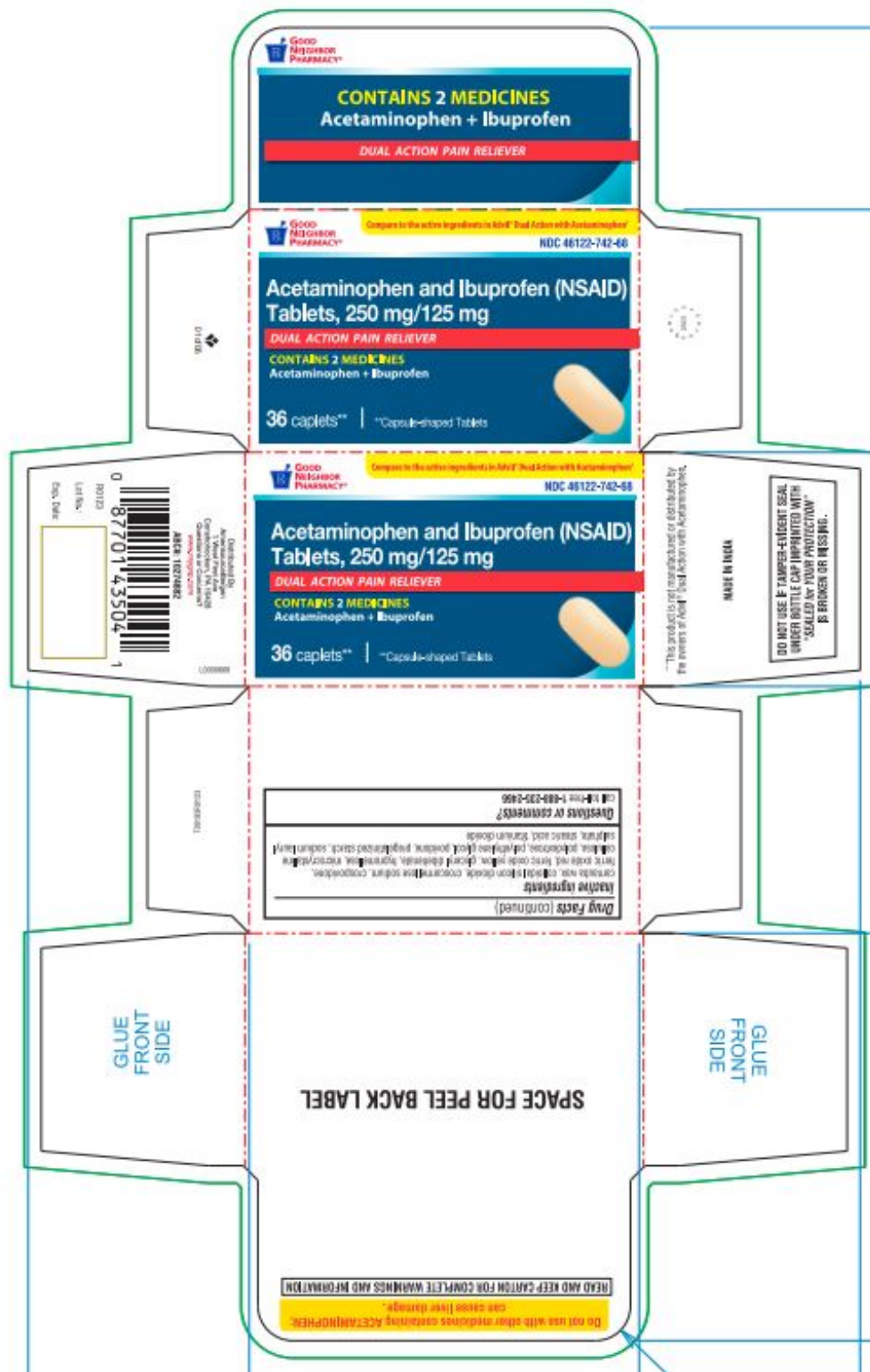
# Inner Ply

<b>Warnings</b> Do not use: • with any other drug containing acetaminophen (see directions for acetaminophen), 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	<b>Drug Facts (continued)</b> Do not use: • with any other drug containing acetaminophen (see directions for acetaminophen), 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	<b>Drug Facts (continued)</b> • you have liver disease • stomach bleeding warning: NSAIDs may cause stomach bleeding, which is sometimes fatal. Risk factors include: • older age • long-term use • use of aspirin, blood thinners, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you have a history of stomach problems, such as heartburn • you have had blood in your stool, black or tarry stools, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you are taking a steroid • you are taking a steroid
	<b>Directions</b> For temporary relief of minor aches and pains due to: • headache • toothache • backache • menstrual cramps • muscular aches • minor pain of arthritis	<b>Drug Facts (continued)</b> • you have liver disease • stomach bleeding warning: NSAIDs may cause stomach bleeding, which is sometimes fatal. Risk factors include: • older age • long-term use • use of aspirin, blood thinners, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you have a history of stomach problems, such as heartburn • you have had blood in your stool, black or tarry stools, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you are taking a steroid • you are taking a steroid

# Base Ply

<b>Drug Facts (continued)</b> • you have liver disease • stomach bleeding warning: NSAIDs may cause stomach bleeding, which is sometimes fatal. Risk factors include: • older age • long-term use • use of aspirin, blood thinners, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you have a history of stomach problems, such as heartburn • you have had blood in your stool, black or tarry stools, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you are taking a steroid • you are taking a steroid	<b>Drug Facts (continued)</b> • you have liver disease • stomach bleeding warning: NSAIDs may cause stomach bleeding, which is sometimes fatal. Risk factors include: • older age • long-term use • use of aspirin, blood thinners, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you have a history of stomach problems, such as heartburn • you have had blood in your stool, black or tarry stools, heart disease, low stomach acid, kidney disease, ulcers, or had a stroke • you are taking a steroid • you are taking a steroid • you are taking a steroid	<b>Directions</b> For temporary relief of minor aches and pains due to: • headache • toothache • backache • menstrual cramps • muscular aches • minor pain of arthritis
<b>Other information</b> • Each capsule contains acetaminophen 325 mg and ibuprofen 100 mg. • Store at 20° to 25° (68° to 77°). Excursions permitted to 15° to 30° (59° to 86°). • Avoid excessive heat above 40° (104°).	<b>Other information</b> • Each capsule contains acetaminophen 325 mg and ibuprofen 100 mg. • Store at 20° to 25° (68° to 77°). Excursions permitted to 15° to 30° (59° to 86°). • Avoid excessive heat above 40° (104°).	<b>Other information</b> • Each capsule contains acetaminophen 325 mg and ibuprofen 100 mg. • Store at 20° to 25° (68° to 77°). Excursions permitted to 15° to 30° (59° to 86°). • Avoid excessive heat above 40° (104°).

Carton



## ACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-742
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	AI
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-742-68	36 in 1 CARTON; Type 0: Not a Combination Product	09/08/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216999	09/08/2023	

**Labeler** - AMERISOURCE BERGEN (007914906)

