ACETAMINOPHEN AND IBUPROFEN - acetaminophen and ibuprofen tablet, film coated Aurohealth LLC

Drug Facts

Active ingredients (in each caplet)

Acetaminophen USP 250 mg

Ibuprofen USP 125 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

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

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

colloidal silicon dioxide, corn starch, hydroxypropyl methylcellulose, lactose monohydrate, pregelatinized starch (corn), sodium starch glycolate, stearic acid, titanium dioxide, triacetin, yellow iron oxide

Questions or comments?

Call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by: **AUROHEALTH LLC** 279 Princeton-Hightstown Road East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/125 mg (10 Caplets Bottle Label)

AUROHEALTH

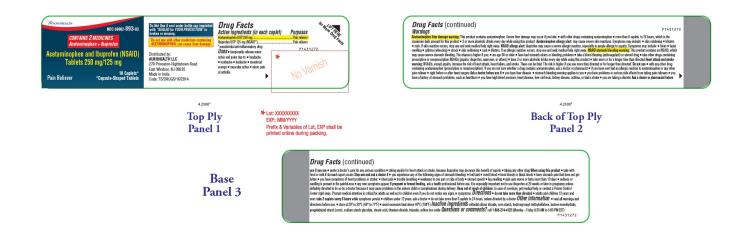
NDC 58602-893-03

CONTAINS 2 MEDICINES Acetaminophen + Ibuprofen

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

Pain Reliever

10 Caplets* *Capsule-Shaped Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/125 mg (10 Caplets Bottle Carton Label)

AUROHEALTH

NDC 58602-893-03

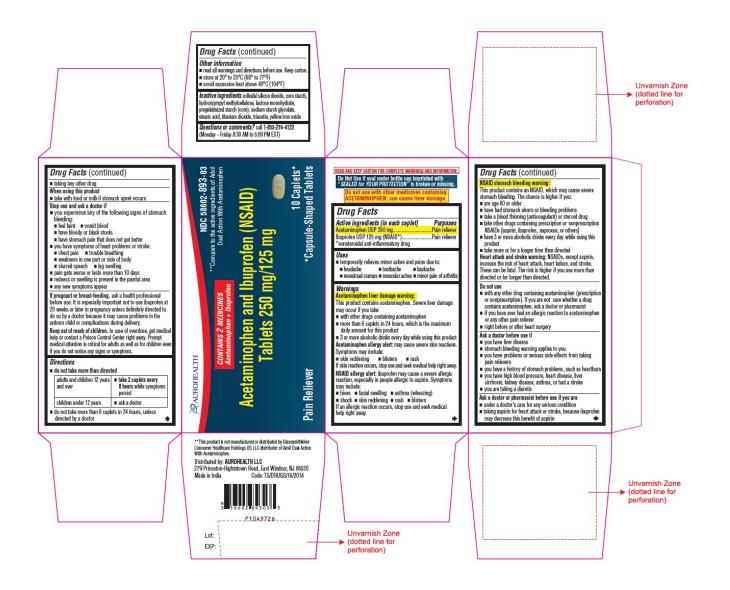
**Compare to the active ingredients of Advil Dual Action With Acetaminophen

CONTAINS 2 MEDICINES Acetaminophen + Ibuprofen

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

Pain Reliever

10 Caplets* *Capsule-Shaped Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/125 mg Blister Carton (2 (1 x 2) Caplets)

AUROHEALTH

NDC 58602-893-61

**Compare to the active ingredients of Advil Dual Action With Acetaminophen

CONTAINS 2 MEDICINES Acetaminophen + Ibuprofen

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

 $\sqrt{}$ Headache

- ✓ Menstrual Cramps
- ✓ Muscular Aches
- √ Toothache

$\sqrt{}$ Minor Pain of Arthritis

Pain Reliever

Each caplet contains Acetaminophen 250 mg and Ibuprofen 125 mg

2 Caplets* *Capsule-Shaped Tablets



SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			ID IBUPROFEN tablet, film coated						
Route of Administration ORAL Active Ingredient/Active Molety Active Ingredient/Active Molety Active Ingredient/Active Molety Active Ingredient Name Basis of Strength Strengt BUPROFEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN (UNII: 36209ITL9D) ACETAMINOPHEN (UNII: 36209ITL9D) Ingredient Name Strengt Ingredient Name Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt Strengt	Product Infor	mation							
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	4	24 in 1 BOTTLE	; Type 0: Not a Combination	on Product					

5	NDC:58602- 893-11	1 in 1 CARTON	03/26/2024	
5		36 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602- 893-14	1 in 1 CARTON	03/26/2024	
6		50 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602- 893-65	1 in 1 CARTON	03/26/2024	
7		72 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602- 893-21	1 in 1 CARTON	03/26/2024	
8		100 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602- 893-29	1 in 1 CARTON	03/26/2024	
9		150 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:58602- 893-62	216 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
11	NDC:58602- 893-35	225 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
12	NDC:58602- 893-44 400 in 1 BOTTLE; Type 0: Not a Combination Product 03/26/2024			
13	893-40			
	NDC:58602- 893-88	Product		
	NDC:58602- 893-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
16	NDC:58602- 893-49	1 in 1 CARTON	03/26/2024	
16		10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
17	NDC:58602- 893-46	1 in 1 CARTON	03/26/2024	
17		18 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
18	NDC:58602- 893-96	1 in 1 CARTON	03/26/2024	
18		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
19	NDC:58602- 893-01	1 in 1 CARTON	03/26/2024	
19		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
20	NDC:58602- 893-85	1 in 1 CARTON	03/26/2024	
20		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
21	NDC:58602- 893-78	1 in 1 CARTON	03/26/2024	
21		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
22	NDC:58602- 893-80	1 in 1 CARTON	03/26/2024	
22		72 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
23	NDC:58602- 893-94	1 in 1 CARTON	03/26/2024	

AND	A	ANDA218359	03/26/2024	
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Information				
30		144 in 1 BOTTLE; Type 0: Not a Combination Product		
	NDC:58602- 893-02	1 in 1 CARTON	12/17/2024	
29		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
29	NDC:58602- 893-61	1 in 1 CARTON	03/26/2024	
28	NDC:58602- 893-95	750 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
27	NDC:58602- 893-79	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
	NDC:58602- 893-99	0 in 1 BOTTLE, PLASTIC; Type 0: Not a 03/26/2024		
25	NDC:58602- 893-84	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	NDC:58602- 893-51	216 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
23		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Labeler - Aurohealth LLC (078728447)

Establishment					
Name	Address	ID/FEI	Business Operations		
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-893), MANUFACTURE(58602-893)		

Revised: 12/2024

Aurohealth LLC