

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*

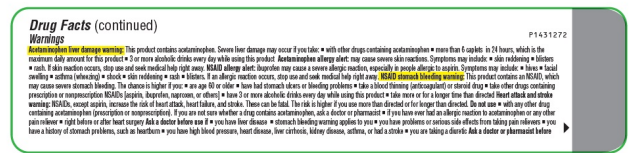
***Capsule-Shaped Tablets**



Top Ply
Panel 1

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be
printed online during packing.

Base
Panel 3



Back of Top Ply
Panel 2

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**

✓ **Minor Pain of Arthritis**

Pain Reliever

**Each caplet contains Acetaminophen 250 mg
and Ibuprofen 125 mg**

2 Caplets*

***Capsule-Shaped Tablets**

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen USP 250 mg Pain reliever
Ibuprofen USP 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

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
 - hives
 - facial swelling
 - asthma (wheezing)
 - shock
 - skin reddening
 - rash
 - blisters
- 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
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 - rash
 - blistersIf 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:

Drug Facts (continued)

- 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
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- you have a history of stomach problems, such as heartburn
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Drug Facts (continued)

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
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When using this product

- take with food or milk if stomach upset occurs

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- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools

Drug Facts (continued)

- 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
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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.



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

- ✓ Headache
- ✓ Menstrual Cramps
- ✓ Muscular Aches
- ✓ Toothache
- ✓ Minor Pain of Arthritis

Pain Reliever

Each caplet contains Acetaminophen 250 mg
and Ibuprofen 125 mg

2 Caplets*

*** Capsule-Shaped Tablets**

Do not use if carton is opened or blister unit is torn or broken.
READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.



N 58602 89361 3

**The product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings US LLC distributor of Advil Dual Action With Acetaminophen.
Distributed by: AUROHEALTH LLC
279 Princeton-Highstown Road, East Windsor, NJ 08520
Made in India
Code: TS0RUS01/2014
P1049955

Lot: EXP:

Drug Facts (continued)

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

Drug Facts (continued)

- 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)

ACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-893
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN
		Strength
		250 mg
		125 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
PALMITOSTEARIC ACID (UNII: Q8Y7S3B85M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics			
Color	YELLOW (Light Yellow to Yellow)	Score	no score
Shape	CAPSULE (Biconvex)	Size	15mm
Flavor		Imprint Code	Al;II
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-893-03	1 in 1 CARTON	03/26/2024	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-893-82	1 in 1 CARTON	03/26/2024	
2		18 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-893-73	1 in 1 CARTON	03/26/2024	
3		20 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-893-07	1 in 1 CARTON	03/26/2024	
4		24 in 1 BOTTLE; Type 0: Not a Combination 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	NDC:58602-893-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
14	NDC:58602-893-88	750 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
15	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	

23		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
24	NDC:58602-893-51	216 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
25	NDC:58602-893-84	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
26	NDC:58602-893-99	400 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	
28	NDC:58602-893-95	750 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2024	
29	NDC:58602-893-61	1 in 1 CARTON	03/26/2024	
29		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
30	NDC:58602-893-02	1 in 1 CARTON	12/17/2024	
30		144 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218359	03/26/2024	

Labeler - Aurohealth LLC (078728447)

Establishment

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