

ACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet, film coated
Bionpharma Inc.

A+Health 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

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

- each caplet contains: **sodium 3 mg**
- read all warnings and directions before use.
- 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.

Distributed by:

BIONPHARMA

Princeton, NJ 08540

MADE IN INDIA

R0524

L0000870

Code: TN/Drugs/
TN00002222/2006
948006836

Lot No.:

Exp. Date:

T00180R0424

PRINCIPAL DISPLAY PANEL

***Compare to the active ingredient in

Advil® Dual Action with

Acetaminophen

NDC 69452-394-64

a+health

Acetaminophen and

Ibuprofen (NSAID)

Tablets, 250 mg/125 mg

DUAL ACTION

PAIN RELIEVER

Contains 2 medicines

216 Caplets**

**capsule-shaped tablets

Front

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NDC 69452-394-64

α+health™

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Drug Facts	
Active ingredients (in each caplet)	Purposes
Acetaminophen, USP 250 mg.....	Pain reliever
Ibuprofen, USP 125 mg (NSAID*)	Pain reliever
*nonsteroidal anti-inflammatory drug	
Uses	
<ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 	

Lot No. 69452-39464
Exp. Date: 3

MADE IN INDIA
Code: TV Drugs/ TM0000222/2006
940008336

PEEL HERE for More Drug Facts

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Distributed by: **BIONPHARMA**
Princeton, NJ 08540

Back Ply-1

<p>Drug Facts (continued)</p> <p>Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> skin reddening blisters rash If skin reaction occurs, stop use and seek medical help right away.</p> <p>NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> hives facial swelling asthma (wheezing) shock skin reddening rash blisters If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>NSAID stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: <ul style="list-style-type: none"> 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.</p>	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> 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 <p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs
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Back Ply-2

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 <p>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.</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>take 2 caplets every 8 hours while symptoms persist</td> </tr> <tr> <td>children under 12 years</td> <td>ask a doctor</td> </tr> </table> <ul style="list-style-type: none"> do not take more than 6 caplets in 24 hours, unless directed by a doctor <p>Other information</p> <ul style="list-style-type: none"> each caplet contains: sodium 3 mg read all warnings and directions before use. store at 20°C to 25°C (68°F to 77°F) avoid excessive heat above 40°C (104°F) <p>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</p> <p>Questions or comments? call toll-free 1-888-235-2466</p>	adults and children 12 years and over	take 2 caplets every 8 hours while symptoms persist	children under 12 years	ask a doctor
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ACETAMINOPHEN AND IBUPROFEN
 acetaminophen and ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-394

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	AI
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-394-64	216 in 1 BOTTLE; 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 - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
RECIPHARM PHARMASERVICES PRIVATE LIMITED		871401927	manufacture(69452-394)

Establishment

Name	Address	ID/FEI	Business Operations
OrBion Pharmaceuticals Private Limited		854403569	manufacture(69452-394)

Revised: 8/2024

Bionpharma Inc.