

ACETAMINOPHEN AND IBUPROFEN- acetaminophen and ibuprofen tablet

RUGBY LABORATORIES

Contains 2 medicines

Dual action

Acetaminophen and Ibuprofen (NSAID) Tablets

250 mg/125 mg

Pain Reliever

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:

- headache
- toothache
- backache
- menstrual cramps
- muscular aches
- minor pain of arthritis

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

Keep out of reach of children

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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.

■ 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.

Acetaminophen and Ibuprofen (NSAD) Tablets

TOP

<p>Rugby NDC 0536-1376-36 Compare to the active ingredients of Advil® Dual Action!</p> <p>Contains 2 Medicines Dual Action</p> <p>Acetaminophen and Ibuprofen (NSAID) Tablets</p> <p>250 mg/125 mg</p> <p>Pain Reliever</p> <p>36 Caplets* (*Capsule-Shaped Tablets)</p>	<p>Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage</p> <p>READ THE DIRECTIONS AND WARNINGS BEFORE USE</p> <p>Drug Facts</p> <p>Active ingredients (in each caplet)</p> <p>Acetaminophen 250 mg Pain reliever Ibuprofen 125 mg (NSAID)** Pain reliever **nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <p>temporarily relieves minor aches and pains due to:</p> <ul style="list-style-type: none"> headache toothache backache menstrual cramps muscular aches minor pain of arthritis 	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>Acetaminophen liver damage warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <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 <p>Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include:</p> <p>Rev. 10/23 R-152 Re-order No. 371134</p> <p>3 05361 37636 9</p> <p>distributed by: ROGEE LABORATORIES Parsippany, NJ 08859 (800) 885-0701 www.rogeelaboratories.com *Rugby® and the Rugby logo are trademarks of their respective owners. This product is not affiliated with the manufacturers of Advil® Dual Action.</p> <p>(CONTINUED ON BACK OF LABEL) Made in India 3000004967 3000000205</p> <p>LOT EXP PEEL HERE</p>
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INSIDE

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> skin reddening blisters rash <p>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:</p> <ul style="list-style-type: none"> hives facial swelling asthma (wheezing) shock skin reddening rash blisters <p>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:</p> <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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 <p>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>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>Drug Facts (continued)</p> <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>
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BASE

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Take with food or milk if stomach upset occurs <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</p>	<p>Drug Facts (continued)</p> <p>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>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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> <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> <p>do not take more than 6 caplets in 24 hours, unless directed</p>	adults and children 12 years and over	take 2 caplets every 8 hours while symptoms persist	children under 12 years	ask a doctor	<p>Drug Facts (continued)</p> <p>by a doctor</p> <p>Other information</p> <ul style="list-style-type: none"> read all warnings and directions before use store at 20 to 25°C (68 to 77°F) avoid excessive heat above 40°C (104°F) <p>Inactive ingredients camellia 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</p> <p>Questions or comments? call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST</p>
adults and children 12 years and over	take 2 caplets every 8 hours while symptoms persist					
children under 12 years	ask a doctor					

ACETAMINOPHEN AND IBUPROFEN

acetaminophen and ibuprofen tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0536-1376

Route of Administration	ORAL
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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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1376-36	36 in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA

ANDA216592

07/15/2023

Labeler - RUGBY LABORATORIES (079246066)

Revised: 12/2023

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