

**DUAL ACTION PAIN RELIEF- acetaminophen, ibuprofen tablet**  
**TIME CAP LABORATORIES, INC.**

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**716R Albertsons 21130-716 Acetaminophen and Ibuprofen Tablets 250 mg/  
125 mg**

***Drug Facts***

***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

***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 (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**

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adults and children 12 years and over	<ul style="list-style-type: none"> <li>• <b>take 2 caplets every 8 hours</b> while symptoms persist</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

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- 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 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients** colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide.

**Questions or comments?** Call **1-877-290-4008**

NDC 49483-716-49



## Dual Action Pain Relief

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

Pain Reliever

144 Caplets\*\* (\*\*Capsule-Shaped Tablets)

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.**

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

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

**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.

**If pregnant or breast-feeding,** ask a health professional before use.  
**Keep out of reach of children.**

**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 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)

**Questions or comments?** Call 1-877-290-4008

Distributed by:

Time-Cap Labs, Inc.

17 Michael Avenue,

Farmingdale, NY 11735

Made in India 716R 1023

40165401 Code No.: 60DRUGS/515

Lot No.:

Exp. Date:

Varnish Omit Area



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

**timely™**

**Dual Action Pain Relief**

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

**Pain Reliever**

**72 Caplets\*\* (\* Capsule-Shaped Tablets)**

Actual Size



Varnish Omit

Varnish Omit

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

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

<p><b>Drug Facts (continued)</b></p> <p><b>Active ingredients (in each caplet)</b> Acetaminophen 250 mg Ibuprofen 125 mg (NSAID) Pain Reliever</p> <p><b>Purposes</b> Acetaminophen 250 mg Ibuprofen 125 mg (NSAID) Pain Reliever</p> <p><b>Uses</b> temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis</p> <p><b>Warnings</b> temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis</p> <p><b>NSAID allergy alert:</b> Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ skin rash ■ hives ■ difficulty breathing ■ swelling of the face, lips, tongue, or throat ■ dizziness ■ fainting ■ lightheadedness ■ blurred vision ■ ringing in the ears ■ watery eyes ■ difficulty swallowing ■ difficulty breathing</p> <p><b>Acetaminophen allergy alert:</b> may cause severe skin reactions. Symptoms may include: ■ 3 or more alcoholic drinks every day while using this product ■ more than 6 caplets in 24 hours, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen</p> <p><b>Acetaminophen liver damage warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take: ■ 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>	<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor before use if:</b> you have liver disease ■ stomach bleeding ■ 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> <p><b>Ask a doctor or pharmacist before use if you are:</b> ■ 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> <p><b>When using this product:</b> ■ take with food or milk if stomach upset occurs</p> <p><b>Stop use and ask a doctor if:</b> ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ chest pain ■ trouble breathing</p> <p><b>Do not use</b> ■ 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> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p> <p><b>NSAID stomach bleeding warning:</b> 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 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</p>
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Varnish Omit

Lot No.:  
Exp Date:



<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor before use if:</b> you have liver disease ■ stomach bleeding ■ 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> <p><b>Ask a doctor or pharmacist before use if you are:</b> ■ 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> <p><b>When using this product:</b> ■ take with food or milk if stomach upset occurs</p> <p><b>Stop use and ask a doctor if:</b> ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ chest pain ■ trouble breathing</p> <p><b>Do not use</b> ■ 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> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p> <p><b>NSAID stomach bleeding warning:</b> 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 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</p>	<p><b>Drug Facts (continued)</b></p> <p><b>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</b></p> <p><b>If pregnant or breast-feeding,</b> 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><b>Keep out of reach of children.</b> 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><b>Directions</b> ■ do not take more than directed</p>
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This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings US LLC, owner of the registered trademark Advil® Dual Action with Acetaminophen.

Distributed by:  
Time-Cap Labs, Inc.  
7 Michael Avenue  
Farmingdale, NY 11735

Made in India  
716R 1023



NDC 49483-716-75



## Dual Action Pain Relief

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

Pain Reliever

72 Caplets\*\* (\*\*Capsule-Shaped Tablets)

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.**

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

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

**Uses** ■ temporarily relieves minor aches and pains due to: headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis

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**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.**

**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 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)

**Questions or comments?** Call 1-877-290-4008  
Distributed by: Time-Carl Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735  
40163001 Code No. 60DRUSS515

Lot No.:  
Exp. Date:

Made in India: 7168 1023  
**Varnish Omit Area**

# DUAL ACTION PAIN RELIEF

acetaminophen, ibuprofen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-716
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRICETIN</b> (UNII: XHX3C3X673)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule Shaped Tablets)	<b>Size</b>	15mm

<b>Flavor</b>		<b>Imprint Code</b>	80	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-716-75	1 in 1 CARTON	10/13/2023	
1		72 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49483-716-49	1 in 1 CARTON	10/13/2023	
2		144 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA216994	10/13/2023		

**Labeler** - TIME CAP LABORATORIES, INC. (037052099)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-716)

Revised: 10/2023

TIME CAP LABORATORIES, INC.