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

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

adults and children 12 years and over

 take 2 caplets every 8 hourswhile 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)

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

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Time-Cap Labs, Inc.
7 Michael Avenue,
Farmingdale, NV 11735
Made in India 716R 1023
40165401 Code No.: GODRUGS/515 Pain Reliever Warnings

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

Exp. Date:

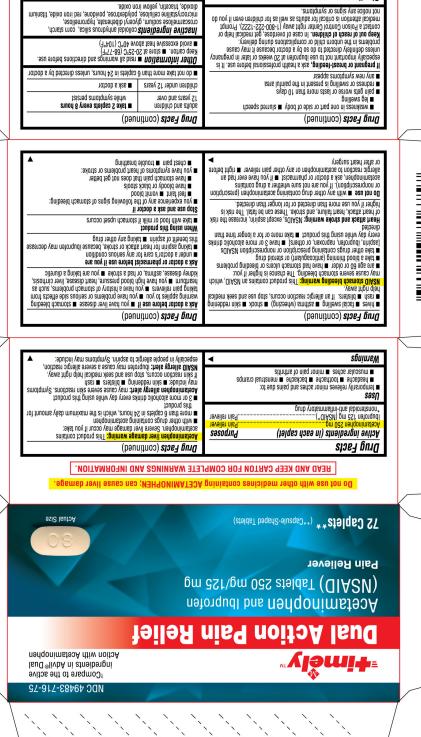


Questions or comments? Call 1-877-290-4008

or symptoms.

Varnish Omit

Exp Date: Lot No.:



Directions

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6

Varnish Omit

Lot No.: Exp Date:

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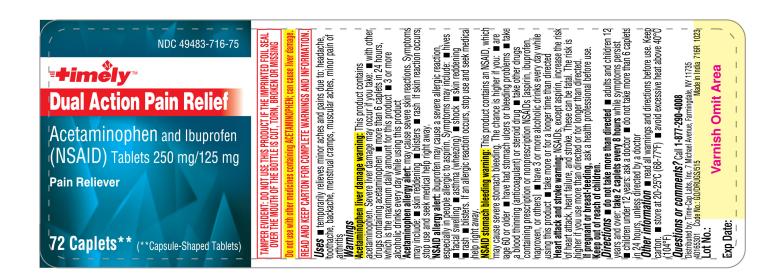
Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735

with Acetaminophen.

¹This product is not manufactured or distributed by Glaxosmithkline Consumer Healthcare Holdings US L owner of the registered trademark Advil® Dual Action

Varnish Omit

EBOTTLE



DUAL ACTION PAIN RELIEF

acetaminophen, ibuprofen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-716	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	125 mg		

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE (UNII: FZ 989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	yellow	Score	no score
Shape	CAPSULE (Capsule Shaped Tablets)	Size	15mm

Flavor	I	Imprint Code	80
Contains			

Packaging				
#	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		

Marketing Information			
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)

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

Revised: 10/2023 TIME CAP LABORATORIES, INC.