

HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet WALGREENS

**477R-Walgreens Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg
Tablets (Dye Free)**

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Pain reliever aid

Uses

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual and menstrual cramps

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis
- any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- 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

- ringing in the ears or loss of hearing occurs
- painful area is red or swollen

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Directions

- **do not use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor


Other information

- store at 20°- 25°C (68°- 77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

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



EXTRA STRENGTH
Headache Relief

Acetaminophen 250 mg, pain reliever
Aspirin (NSAID) 250 mg, pain reliever
Caffeine 65 mg, pain reliever aid

Free + Pure is:

- No artificial flavors
- No synthetic colors
- Gluten free*
- Non-GMO

100 caplets[†]
(capsule-shaped tablets)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Uses: Temporarily relieves minor aches and pains due to: headache, a cold, arthritis, muscular aches, toothache, premenstrual and menstrual cramps

Warnings:
Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ strick

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

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 thinner (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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ■ do not use more than directed ■ drink a full glass of water with each dose ■ adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours ■ children under 12 years: ask a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.** ■ store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package

Questions or comments? Call **1-877-290-4008** WFFP0R0424-F
Walgreens, Inc., Deerfield, IL 60015 100% SATISFACTION GUARANTEED
*Contains less than 10ppm of gluten. NDC 0363-1012-01 ITEM 407234 W00000-0000-0
477R 0224

Lot No.: _____
Exp. Date: _____

Varnish Omit Area

Side of Package

Varnish/Print Omit Area



ITEM #42724 W00 000-0000-0
©2022 Walgreen Co.
100% SATISFACTION GUARANTEED
DEERFIELD, IL 60015
DISTRIBUTED BY: WALGREEN CO.
LOT # 1917 05451



Bottom of Package

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID)*	Pain reliever
Caffeine 65 mg	Pain reliever aid

*nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash if a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

Back of Package

Drug Facts (continued)

- have had stomach ulcers or bleeding problems
- take a blood thinner (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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, good, or arthritis
- any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- you experience any of the following signs of stomach bleeding:
 - red or black stools
 - vomiting blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - ringing in the ears or loss of hearing occurs

Top of Package

Drug Facts (continued)

- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

carbazole wax, colloidal silicon dioxide, hydroxyethylcellulose, microcrystalline cellulose, mineral oil, polydioxane, pregelatinized starch, sodium starch glycolate, stearic acid

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

*Contains less than 20ppm of gluten

Front of Package

Walgreens free+pure

EXTRA STRENGTH

Headache Relief

Acetaminophen 250 mg, pain reliever, aspirin (NSAID) 250 mg

Pain reliever, caffeine 65 mg, pain reliever aid

Compare to the active ingredients in Excedrin® Extra Strength*

Actual size
100 caplets†

*Free + Pure is:
• No artificial flavors
• No synthetic colors
• Gluten free*
• Non-GMO

Varnish/Print Omit Area

Side of Package

This product may be manufactured or distributed by Healden Group of companies, owner of the registered trademark Extra Strength.

WFPORG0424-F

Front of Package

Walgreens free+pure

EXTRA STRENGTH

Headache Relief

Acetaminophen 250 mg, pain reliever, aspirin (NSAID) 250 mg

Pain reliever, caffeine 65 mg, pain reliever aid

Compare to the active ingredients in Excedrin® Extra Strength*

Actual size
100 caplets†

*Free + Pure is:
• No artificial flavors
• No synthetic colors
• Gluten free*
• Non-GMO

Varnish/Print Omit Area

Walgreens free+pure

EXTRA STRENGTH

Headache Relief

Acetaminophen 250 mg, pain reliever
Aspirin (NSAID) 250 mg, pain reliever
Caffeine 65 mg, pain reliever aid

†Free + Pure is:
• No artificial flavors
• No synthetic colors
• Gluten free
• Non-GMO
24 caplets†
(capsule-shaped tablets)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Temporarily relieves minor aches and pains due to: headache, a cold, arthritis, muscular aches, toothache, premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness. **Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash if a skin reaction occurs, stop use and seek medical help right away. **Allergy alert:** Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 thinner (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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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.

Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

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

DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED
ITEM #42724 Walgreen Co. NDC 0885-7012-42 ITEM 422594 W00000-0000-0
4779 0224

THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING Store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F) Use by expiration date on package

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

DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED
ITEM #42724 Walgreen Co. NDC 0885-7012-42 ITEM 422594 W00000-0000-0
4779 0224

Lot No.:
Exp. Date:



HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-7012
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Capsule shaped tablet)	Size	17mm
Flavor		Imprint Code	TCL477
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7012-42	1 in 1 CARTON	05/01/2024	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-7012-01	1 in 1 CARTON	05/01/2024	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2024	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(0363-7012)