

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet

Walgreens

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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 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
- shock
- asthma (wheezing)

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

Ask a doctor or pharmacist before use if you are

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

Stop use and ask doctor if

- an allergic reaction occurs. Seek medical help right away.
 - any new symptoms appear
- 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
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

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 during the last 3 months of 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. 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 and over: take 2 caplets every 6 hours; do not take more than 8 caplets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients

carnauba wax**, colloidal silicon dioxide, corn starch, hypromellose, microcrystalline cellulose, mineral oil**, polyethylene glycol**, povidone, sodium starch glycolate**, stearic acid, talc**, titanium dioxide

**contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Excedrin® Extra Strength active ingredients††

Headache Relief

ACETAMINOPHEN / ASPIRIN (NSAID) /

PAIN RELIEVER / CAFFEINE / PAIN RELIEVER AID

EXTRA STRENGTH

CAPLETS

††This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY: WALGREEN CO

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Package Label



TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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
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 ■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache
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Allergy alert: Aspirin may cause a severe allergic reaction, which may include:
 ■ hives ■ facial swelling ■ shock ■ asthma (wheezing)
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.
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
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Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
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Drug Facts (continued under label)
 Walgreens Pharmacist Recommended
 Walgreens Pharmacy Survey
 †This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.
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 REV0718-F
 REV-0519

ITEM 905195 W10064-0519-F
 3 11917117718 2
 Lot No.: Exp. Date:



PLD-F1036
 LB005952

Drug Facts (continued)
 ■ 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 asthma ■ you are taking a diuretic ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
Ask a doctor or pharmacist before use if you are
 ■ taking a prescription drug for diabetes, gout, or arthritis
 ■ taking 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. ■ any new symptoms appear ■ you experience any of the following signs or 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 ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ painful area is red or swollen
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Other information ■ store between 20°-25°C (68°-77°F)
Inactive ingredients carmelum wax** coloidal silicon dioxide, corn starch, hypromellose, microcrystalline cellulose, mineral oil**, polyethylene glycol**, polydioxane, sodium starch glycolate**, stearic acid, talc**, titanium dioxide**
 **contains one or more of these ingredients
Questions or comments? Call 1-877-733-3835 Monday-Friday 9AM-5PM EST

WALGREENS Extra Strength Headache Relief

HEADACHE RELIEF EXTRA STRENGTH			
acetaminophen, aspirin, caffeine tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0625
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	TCL370;S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0625-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	06/30/2016	

Labeler - Walgreens (008965063)

Revised: 7/2019

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