

HEADACHE RELIEF- acetaminophen, aspirin, and caffeine tablet
We Care Distributor Inc.

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.

Headache Relief - Acetaminophen, Aspirin and Caffeine

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purposes</i>
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
 - sinusitis
 - toothache
 - premenstrual & 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

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

- adult takes more than 8 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 tablets in 24 hours
- 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 heart beat.

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 not been drinking fluids
- 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
- you have lost a lot of fluids due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are taking

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- 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 appear

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 (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 and over:** take 2 tablets every 6 hours; do not take more than 8 tablets in 24 hours
- **children under 12 years:** ask a doctor

Other information

- store at 25 °C (77°F) excursions permitted between 15-30°C(59-86°F)
- read all product information before using. Keep this box for important information

Inactive ingredients

hypromellose, microcrystalline cellulose, polyethylene glycol, polyvinyl pyrrolidone, pregelatinized starch, silicon dioxide, stearic acid, talc

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

**Compare to the Active Ingredients in
*EXCERDRIN EXTRA STRENGTH***

Acetaminophen, Aspirin (NSAID) and Caffeine

TO OPEN

PUSH IN TAB AND PULL OUT

25 Pouches of 2 Caplets Each

NDC: 70005-004-50

SEE NEW WARNINGS INFORMATION



HEADACHE RELIEF

COMPARE TO

Excedrin[®] Extra Strength

ACTIVE INGREDIENTS †

Acetaminophen,
Aspirin (NSAID) and Caffeine

• Pain Reliever / Pain Reliever Aid

†This product is not manufactured or distributed by
Novartis Consumer Health, Inc., owner of the
registered trademark Excedrin[®] Extra Strength.



25 Pouches of 2 Coated Tablets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredients (in each caplet)	Purpose
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Uses

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

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: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- asthma (wheezing)

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

- more than 8 tablets 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 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 have asthma
- you are taking a diuretic

Drug Facts (continued)

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

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - any allergic reaction occurs. Seek medical help right away.
 - any new symptoms appear
 - 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

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.

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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 tablets every 6 hours
- do not take more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 25 °C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients hypromellose, microcrystalline cellulose, polyethylene glycol, polyvinyl pyrrolidone, pregelatinized starch, silicon dioxide, stearic acid, talc

Questions or comments?
1-888-705-WE CARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

Manufactured For / Distributed By:
We Care Distributor Inc.
Hermitage, TN 37076
www.wecaredistributor.com

DO NOT USE IF POUCH IS BROKEN OR TORN



HEADACHE RELIEF

acetaminophen, aspirin, and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-004
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6IU)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	ET29
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-004-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-004-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-004-02	2 in 1 POUCH		
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/09/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-004)

Revised: 2/2016

We Care Distributor Inc.