

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin and caffeine tablet
Amerisource Bergen

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

Purpose

Pain reliever

Pain reliever

Pain reliever aid

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

- 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 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 an NSAID's (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 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

- 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 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 right away: 1-800-222-1222. 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; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at controlled room temperature 20⁰ - 25⁰ C (68⁰ - 77⁰ F)
- excursions permitted to 15⁰ C to 30⁰ C (59⁰ -86⁰ F)
- do not use if imprinted safety seal under cap is broken or missing
- **this product is not manufactured or distributed by Novartis Consumer Health, owner of the registered trademark Excedrin® Extra Strength

Inactive ingredients

hypromellose, maltodextrin, microcrystalline cellulose, polydextrose, polyvinylpyrrolidone, pregelatinized starch, silica, starch, stearic acid, talc, titanium dioxide, and triglycerides.

Questions or comments?

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

Principal Display Panel

100453Q3

PRINT SIDE GLUE

v0x04

NO PRINT
NO VARNISH
NO COATINGNO PRINT
NO VARNISH
NO COATING

Drug Facts (continued)

of 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/reducer of inflammation (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 ■ 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 drug for asthma, or any other drug, or

Drug Facts (continued)

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 ■ painful area is red in the ears or loss of hearing occurs ■ ringing 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 right away: **1-800-222-1222**. Quick medical attention is critical for adults as well as for children even if you do

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Acetaminophen 250 mg
Aspirin 250 mg (NSAID)*
Pain reliever
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 ■ menstrual & menstrual cramps

Warnings
Hay'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, it changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Hay's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may cause asthma, hives, or other allergic symptoms.

Drug Facts (continued)

Purposes
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,

GOOD NEIGHBOR PHARMACY® Extra Strength

Headache Relief

Pain Reliever/Pain Reliever Aid

100 caplets

GOOD NEIGHBOR PHARMACY®

Compare to Excedrin® Extra Strength active ingredients™

NDC 46122-104-78

See New Warnings Information Extra Strength

Headache Relief
acetaminophen, 250 mg aspirin, 250 mg (NSAID)*
caffeine, 65 mg
Pain Reliever/Pain Reliever Aid

100 caplets

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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Lot No.:
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Drug Facts (continued)

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; not more than 8 caplets in 24 hours ■ children under 12 years: ask a doctor

Other information ■ store at controlled room temperature 20°-25°C (68°-77°F) ■ excursions permitted to 15°C to 30°C (59°-86°F) ■ do not use if imprinted safety seal under cap is broken or missing ■ **This

Inactive ingredients hydroxyzine, mafenide, microcrystalline cellulose, polydextrose, stearic acid, talc, titanium dioxide and trihydrates

Questions or comments? Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

Drug Facts (continued)

product is not manufactured or distributed by Hoechst Consumer Health, owner of the registered trademark Excedrin® Extra Strength

Extra strength Headache relief

HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin and caffeine tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:46 122-104

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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE K15 (UNII: E54VE15114)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	2793
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-104-78	1 in 1 BOX		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/15/2012	

Labeler - Amerisource Bergen (007914906)