

EXTRA STRENGTH HEADACHE RELIEF- extra strength headache relief tablet, coated **Healthlife of USA**

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.

Extra Strength Headache Relief

Drug Facts

Purpose

Pain reliever, Pain reliever aid

Active Ingredient (in each caplet)

Acetaminophen 250mg

Aspirin 250mg

Caffeine 65mg

Uses

- Temporarily relieves minor aches and pains due to:
- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- 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 behaviour 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
- shock
- 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, food, 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

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
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- an 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.

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)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

- Corn starch
- Crospovidone
- Hypromellose
- Microcrystalline cellulose
- Povidone
- Propylene glycol
- Sodium Lauryl sulfate
- Sodium starch glycolate
- Stearic acid
- Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM- 5PM EST or www.healthlifeofusa.com

Extra Strength Headache Relief
Acetaminophen 250mg / Pain Reliever
Aspirin 250mg (Nsaid) / Pain Reliever
Caffeine 65mg / Pain Reliever Aid
24 Caplets

Compare to Excedrin® Extra Strength active ingredients

Distributed by:
Healthlife of USA LLC
Rahway
NJ 07065
www.healthlifeofusa.com

EXTRA STRENGTH HEADACHE RELIEF

extra strength headache relief tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69517-105

Route of Administration

ORAL

Drug Facts (continued)

Questions or comments?
Call toll free 1-844-832-1138
Monday through Friday 9AM - 5PM EST or
www.healthlifeusa.com

RETAIN CARTON FOR COMPLETE DRUG FACTS

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

NDC 69517-105-24

HealthLife

Extra Strength

Headache Relief

Acetaminophen 250 mg / Pain Reliever
Aspirin 250 mg (NSAID) / Pain Reliever
Caffeine 65 mg / Pain Reliever Aid

24 CAPLETS

SEE NEW WARNINGS INFORMATION

Compare to Excedrin® Extra Strength active ingredients!

Distributed by: HealthLife of USA LLC
Rahway, NJ 07065
www.healthlifeofusa.com



Drug Facts (continued)

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COATING FREE AREA

Drug Facts (continued)

- 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 or ulcers happen to you
 - You have a history of stomach problems,
 - Such as heartburn, blood pressure, heart disease, liver cirrhosis or kidney disease
 - You have asthma
 - You are taking a diuretic
- 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
 - Have bloody or black stools
 - Vomit blood
 - Have stomach pain that does not get better

Drug Facts (continued)

- An allergic reaction occurs. Seek medical help right away.
- Any new symptoms appear
- Pain gets worse or lasts for more than 10 days
- Ever gets worse or lasts for more than 3 days
- Coated 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.
- 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)
 - TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**
- Inactive ingredients** corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

COATING FREE AREA

Drug Facts (continued)

COATING FREE AREA

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 250 mg — Pain reliever
Aspirin 250 mg (NSAID) — Pain reliever
Caffeine 65 mg — Nonsteroidal anti-inflammatory drug

Uses

- Temporarily relieves minor aches and pains due to:
 - Headache
 - Cold
 - Arthritis
 - Muscular aches
 - Sinusitis
 - 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: Aspirin may cause a severe allergic reaction, which may include:

- Hives
- Shock
- 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

See a health care provider if:

- Stomach bleeding warning: This product contains an NSAID, which may cause a stomach bleed. The chance of high or low blood pressure, heart disease, stroke, or other serious health problems increases if you are taking these or other drugs that may affect the blood.
- See a blood thinning (anticoagulant) or steroid drug

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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

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	18 mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-105-24	1 in 1 CARTON	05/31/2017	
1		24 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 not final	part343	05/31/2017	

Labeler - Healthlife of USA (079656178)**Establishment**

Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-105)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals limited		915664486	manufacture(69517-105) , pack(69517-105)

