

EXTRA STRENGHT HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet
Spirit Pharmaceutical LLC

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

<i>Active ingredient (in each caplet)</i>	<i>Purpose</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

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.

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 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 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 prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition
- a blood thinning (anticoagulant) or steroid drug

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

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

Overdose Warning

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. 1(800) 222-1222

Directions

- **do not use more than directed (see Overdose Warning)**
- 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

- **Each caplet contains:** Magnesium 0.58 mg
- store at controlled room temperature 20° - 25° C (68° - 77° F)
- read all product information before using. Keep this box for important information

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

Questions or comments

1-888-333-9792

Principal Display Panel

COMPARE TO THE ACTIVE
INGREDIENTS OF EXCEDRIN®
EXTRA STRENGTH*

EXTRA STRENGHT

HEADACHE RELIEF

ACETAMINOPHE, ASPIRIN (NSAID) AND CAFFEINE

PAIN RELEIVER / PAIN RELEIVER AID



NDC 68210-0107-1

Compare to active ingredients in Excedrin® Extra Strength†

EXTRA STRENGTH

HEADACHE RELIEF

Acetaminophen,
Aspirin (NSAID)
and Caffeinepain reliever/
pain reliever aid

100 caplets



Actual Size

Compare to active ingredients in
Excedrin® Extra Strength†EXTRA STRENGTH
HEADACHE
RELIEFAcetaminophen,
Aspirin (NSAID)
and Caffeinepain reliever/
pain reliever aid

300 caplets



Actual Size

**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 Temporarily relieves minor aches and pains due to:

- headache
- cold
- arthritis
- muscle 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: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin rash
- hives
- skin redness
- blisters
- rash

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

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 a nonsteroidal anti-inflammatory drug (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 thinner (anticoagulant) or steroid drug
- take other drugs containing NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take 3 or more alcoholic drinks every day while using this product

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.

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

Distributed By:
Novartis Pharmaceuticals, LLC
Boston, MA, NY 11779
REV 06/18
Made in India

Drug Facts (continued under label)

ITEM#6822-2



0 14 0 2 3 2 1 6 8 9 2 2 2

LOT:

EXP:

**Drug Facts (continued)**

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 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
- high blood pressure
- you have asthma

Ask a doctor or pharmacist before use if you are taking:

- any other drug containing an NSAID (prescription or non-prescription)
- a prescription drug for diabetes, gout or arthritis
- any other drug, or are under a doctor's care for any serious condition
- a blood thinner (anticoagulant) or steroid drug

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

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. 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: 1-800-222-1222

Directions

- do not take more than directed (see Overdose warning)
- 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

- each caplet contains magnesium 0.50 mg
- store at controlled room temperature 20° - 25° C (68° - 77° F)
- read all product information before using.

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, polyene, pregelatinized starch, stearic acid, talc

Questions or comments? 1-888-333-9792

EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0107
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (capsule shaped, biconvex)	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0107-1	1 in 1 CARTON	03/10/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0107-3	300 in 1 PACKAGE; Type 0: Not a Combination Product	03/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/10/2020	

Labeler - Spirit Pharmaceutical LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
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ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0107)
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Revised: 3/2020

Spirit Pharmaceutical LLC