

HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet, coated **Strive Pharmaceuticals 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.

RIGHT REMEDIES Headache Relief

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 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 • 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, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasional 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 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 before or pharmacist before use if you are taking

- 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 occur

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. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

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 tablet contains:** sodium 5.1mg (low sodium)
- store at room temperature between 20-25°C(68-77°F)
- avoid excessive heat, cold and humidity
- close cap tightly after use
- read all product information before using.

Inactive ingredients

croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol, polyvinyl alcohol, povidone, purified talc, sodium lauryl sulphate, sodium starch glycolate, starch, titanium dioxide

Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm EST

Compare to the active ingredients of **Excedrin® Extra Strength***

RIGHT REMEDIES

EXTRA STRENGTH

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING FROM BOTTLE

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

Distributed by:
Strive Pharmaceuticals Inc.
East Brunswick, NJ 08816

Product of India
Packaged and Quality Assured in the USA

REV.00-062021

Packaging



RIGHT REMEDIES Compare to the active ingredients of Excedrin® Extra Strength*
NDC 70692-142-31

EXTRA STRENGTH Headache Relief

ACETAMINOPHEN, ASPIRIN (NSAID) and CAFFEINE
Pain reliever, Pain reliever aid

300 caplets

Actual Size

DRUG FACTS: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING FROM BOTTLE

Drug Facts

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Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg(NSAID)*.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid
*nonsteroidal anti-inflammatory drug	

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Lot: No Varnish

LB7069214231 LOT:
REV.00-062021 EXP:

3 70692 00030 6

PEEL HERE

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PEEL HERE

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Drug Facts (Continued)

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Inactive ingredients
 croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol, polyvinyl alcohol, povidone, purified talc, sodium lauryl sulphate, sodium starch

glycolate, starch, titanium dioxide

Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm EST

HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-142
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	RECTANGLE	Size	18mm
Flavor		Imprint Code	S142
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-142-31	300 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/06/2023	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 4/2023

Strive Pharmaceuticals Inc.