

EXTRA STRENGTH HEADACHE RELIEF GELTABS- acetaminophen, aspirin, caffeine tablet

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 EXTRA STRENGTH Headache Relief

Drug Facts

Active ingredients (in each geltab)

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 geltabs 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 geltabs every 6 hours; not more than 8 geltabs in 24 hours
- children under 12 years: ask a doctor

Other information

- **each geltab contains:** sodium 4mg (very low sodium) and potassium 3mg
- store at room temperature between 20-25°C(68-77°F)
- avoid excessive heat, cold and humidity

Inactive ingredients

corn starch, D&C yellow # 10 aluminum lake, edible black ink, ethyl cellulose, FD&C blue #1, FD&C blue #1 aluminum lake, FD&C red # 40 aluminum lake, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, microcrystalline cellulose, povidone, pregelatinized potato starch, purified water, sorbitol sorbitan solution, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

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

RIGHT REMEDIES

Compare to the active ingredients of **Excedrin® 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

Made in UAE

Packaged and Quality Assured in the USA

REV.00-062021

Packaging



EXTRA STRENGTH
Headache Relief
 ACETAMINOPHEN, ASPIRIN (NSAID) and CAFFEINE
 Pain reliever, Pain reliever aid
 200 gels
 Actual Size

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Drug Facts
Active ingredients (in each geltab)
 Acetaminophen 250 mg.....Pain reliever
 Aspirin 250 mg(NSAID)*.....Pain reliever
 Caffeine 65 mg.....Pain reliever
 *nonsteroidal anti-inflammatory drug

Uses
 Temporarily relieves minor aches and pains due to:
 ■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache
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Warnings
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Allergy alert: Acetaminophen may cause skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
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 Strive Pharmaceuticals, East Brunswick, NJ
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LOT: LB7069213220
 EXP: REV.00-062021

3 70692 00022 1
 No Varnish
 PEELED HERE

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 REV.00-062021 EXP:

Drug Facts (Continued)

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Other information
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Inactive ingredients
 corn starch, D&C yellow # 10 aluminum lake, edible black ink, ethyl cellulose, FD&C blue #1, FD&C blue #1 aluminum lake, FD&C red # 40 aluminum lake, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, microcrystalline cellulose, povidone, pregelatinized potato starch, purified water, sorbitol sorbitan solution, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?
 1-888-577-8033 Monday-Friday 8am-4pm EST

EXTRA STRENGTH HEADACHE RELIEF GELTABS

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-132
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, POTATO (UNII: 8I089SAH3T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white, green (White and Green)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	S77

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-132-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/05/2023	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 5/2023

Strive Pharmaceuticals Inc.