

ACETAMINOPHEN 250MG ASPIRIN 250MG CAFFEINE 65MG- acetaminophen 250mg aspirin 250mg caffeine 65mg tablet
CVS Pharmacy

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.

CVS Headache Relief Geltabs
Acetaminophen 250mg, Aspirin 250mg, Caffeine 65mg

Acetaminophen 250mg

Aspirin 250mg

Caffeine 65mg

ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow No. 10 lake, ethyl cellulose, FD&C blue No. 1 lake, FD&C red No. 40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, povidone, pregelatinised starch, propylene glycol, shellac glaze, sorbitol sorbitan, stearic acid, talc, titanium dioxide, triacetin.

- Do not use more than directed
- 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

Temporarily relieves minor aches and pains due to:

Headache, a cold, arthritis, muscular aches, toothache, premenstrual and menstrual cramps

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 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 contains acetaminophen, 3 or more alcoholic drinks every day while using this product.

Stomach bleeding warning: This 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 product, take more or for a longer time than direct.

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 acetaminophen, aspirin, or any other pain reliever/ fever, 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 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 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.

Keep out of reach of children.

OVERDOSE WARNING: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

Pain reliever

Pain reliever

Pain reliever aid

- 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. Keep box for important information.



Compare to the active ingredients in Tylenol Extra Strength

GelTabs

NDC 59779-232-23

EXTRA STRENGTH

Headache Relief

ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE

Pain reliever,
Pain reliever aid



Actual Size

20 GELTABS



Drug Facts (continued)

- any other drug, or are under a doctor's care for any serious condition
 - an allergic reaction occurs. Seek medical help right away.
 - you experience any of the following signs of stomach bleeding:
 - red fruit
 - 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 3 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:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.
- 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 gel tabs every 6 hours, not more than 8 gel tabs in 24 hours
 - children under 12 years: ask a doctor

Drug Facts (continued)

- 3 or more alcoholic drinks every day while using this product 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
- Caution 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 heart disease, irritability, sleeplessness, and occasionally a palp 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 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 or kidney disease, or kidney disease
 - you are taking a diuretic
 - you have asthma
- Ask a doctor or pharmacist before use if you are taking**
- a prescription drug for diabetes, gout, or arthritis

Drug Facts (continued)

- Other information**
- store at room temperature between 20-25°C (68 to 77°F)
 - avoid excessive heat, cold and humidity
 - close cap tightly after use
 - read all product information before using. **Keep outer box for full information.**
- Inactive ingredients** ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow no. 10 lake, ethyl cellulose, FD&C blue no 1 lake, FD&C red no 40 lake, gelatin, glycerin, hydroxypropyl methylcellulose, isopropyl alcohol, isopropyl alcohol-butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polysorb 65/70A00, povidone K 30, pregelatinized starch, propylene glycol, purified water, shellac glaze, stearic acid, talc, titanium dioxide, triacetin
- Questions or comments? 1-800-577-8033**

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

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Drug Facts

- Active ingredients (in each gel tab)**
- 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
 - toothache
 - premenstrual & menstrual cramps
- Warnings**
- Refrain from use:** Children and teenagers who have or are recovering from chicken pox or the 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 redness
 - hives
 - skin rash
 - itching
 - swelling
 - blistering
 - itching
- 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
- Use warning:** This product contains acetaminophen. Severe liver damage may occur if you take:
 - more than 8 gel tabs in 24 hours, which is the maximum daily amount
 - with other drugs containing acetaminophen

Exp. Date:

Lot No.:
CT5977929223 REV100-112020

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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FERROSO FERRIC OXIDE (UNII: XMOM87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
STARCH, CORN (UNII: O8232NY3SJ)	
AMMONIA (UNII: 5138Q19F1X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TALC (UNII: 7SEV7J4R1U)	
SHELLAC (UNII: 46N107B71O)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	green (Dark Green - White)	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:69842-592-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
2	NDC:69842-592-23	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/01/2021	

Labeler - CVS Pharmacy (062312574)

Revised: 7/2023

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