

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

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 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 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
Excedrin® Extra Strength†

Geltabs

MDC 59779-132-23

EXTRA STRENGTH

Headache Relief

ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE

Pain reliever,
Pain reliever aid

20 GELTABS

Actual Size



Drug Facts (continued)

- any other drug, or rate 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 or 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 WARNINGS: 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 gels tabs every 6 hours, not more than 8 gels tabs in 24 hours
 - children under 12 years: ask a doctor

Drug Facts (continued)

- 63 or more a chronic drinker 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

Ask a doctor or pharmacist before use if you are taking ■ you are taking a diuretic ■ you have asthma ■ 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 methyl cellulose, isopropyl alcohol, isopropyl alcohol-butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polysorb 85/70/0/0, povidone K 30, pregelatinized starch, propylene glycol, purified water, shellac glaze, stearic acid, talc, titanium dioxide, triacetin
- Questions or comments? 1-888-577-8033**

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

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X XXXXXX XXXXXX X

Exp Date:
Lot No.:

CVS977913223 REV00-112020

Drug Facts

Active ingredients (in each geltab)

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

- a cold
- arthritis
- muscular aches
- toothache
- premenstrual & menstrual cramps


Warnings

Heads warnings: 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 redness, 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 gels tabs in 24 hours, which is the maximum daily amount, with other drugs containing acetaminophen.



Compare to the active ingredients in
Excedrin® Extra Strength
Gel tabs


NDC 59779-132-20

EXTRA STRENGTH

Headache Relief

ACETAMINOPHEN 250 mg
ASPIRIN (NSAID) 250 mg
CAFFEINE 65 mg

Pain reliever,
Pain reliever aid



Actual Size

200 GELTABS

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts	<p>Purposes Pain reliever Pain reliever aid Pain reliever aid</p> <p>Active ingredients (in each gel tab) Acetaminophen 250 mg Aspirin 250 mg (NSAID) Caffeine 65 mg Non-steroidal anti-inflammatory drug</p> <p>Uses Temporarily relieves minor aches and pains due to: ■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache ■ menstrual cramps</p> <p>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. Alergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ hives ■ rash If a skin reaction occurs, stop use and seek medical help right away. Alergy 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 3 gel tabs 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</p>
Drug Facts (continued under label)	<p>This product is not manufactured or distributed by CVS Consumer Healthcare, distributor of Excedrin® Extra Strength. Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02896 © 2021 CVS/Pharmacy CVS.com® 1-800-SHOP CVS Made in U.A.E. TV-37388 #342595 LB5977913220 REV.00-122020</p>

FPO 100%

UPC# 050428256619

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LABEL FRONT

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[177.8]

Drug Facts (continued)

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 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: 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

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.

Inactive ingredients
ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, DCC yellow no. 10 lake, atyl cellulose, FD&C blue no. 1 lake, FD&C red no. 40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, isopropyl alcohol, isopropyl alcohol-butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polyorb 8577(00), polyorb K 30, pregelatinized starch, propylene glycol, purified water, stearic acid, talc, titanium dioxide, triacetin

Questions or comments? 1-888-57-9823

LABEL REVERSE

7

Adhesive Area
All else is deadened

ACETAMINOPHEN 250MG ASPIRIN 250MG CAFFEINE 65MG		
acetaminophen 250mg aspirin 250mg caffeine 65mg tablet		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:69842-591

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, UNSPECIFIED (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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
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:69842-591-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
2	NDC:69842-591-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
3	NDC:69842-591-23	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 Drug	M013	02/01/2021	

Labeler - CVS Pharmacy (062312574)

Revised: 12/2024

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