

ACETAMINOPHEN , ASPIRIN AND CAFFEINE- acetaminophen , aspirin and caffeine capsule
Softgel Healthcare Pvt Ltd

Acetaminophen 250mg, Aspirin 250mg and Caffeine 65mg geltabs

Active ingredients (in each geltab)

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

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

Other information

- 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 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, microcrystalline cellulose, pregelatinized potato starch, purified water, pvpk-30, sorbitol sorbitan solution, stearic acid, talc, titanium dioxide, triacetin.

<u>ACETAMINOPHEN 250MG, ASPIRIN 250MG AND CAFFEINE 65MG GELTABS</u>				Imprint
Each geltab Contains:				
(Acetaminophen USP 250mg, Aspirin USP 250mg and Caffeine USP 65mg)				
BATCH NO	:	NDC NO	:	35916-0709-1
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
<u>WARNING: KEEP OUT OF REACH OF CHILDREN</u>				
<u>STORAGE</u>				
STORE AT ROOM TEMPERATURE BETWEEN 20-25°C (68-77°F)				
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.				
CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.				
MANUFACTURED BY:		MANUFACTURED FOR		
SOFTGEL HEALTHCARE PVT. LTD.,				
SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,				
PUDUPAKKAM, CHENGALPATTU,				
TAMILNADU 603 103, INDIA (IND)				
LABELLER CODE: 35916				
LIC NO:XXXX				
<u>CAUTION</u> : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”				

acetaminophen , aspirin and caffeine capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0709
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SHELLAC (UNII: 46N107B71O)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
STARCH, POTATO (UNII: 8I089SAH3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green (Dark green - white)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0709-1	1500 in 1 BAG; Type 0: Not a Combination Product	01/10/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/08/2026	

Labeler - Softgel Healthcare Pvt Ltd (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd