

**ACETAMINOPHEN , CAFFEINE AND PYRILAMINE MALEATE- acetaminophen ,
caffeine and pyrilamine maleate capsule, liquid filled
Softgel Healthcare Pvt Ltd**

**Acetaminophen 500mg, Caffeine 60mg, Pyrilamine Maleate 15mg softgelatin
capsules**

Active ingredient (in each softgelatin capsule)

Acetaminophen 500mg
Caffeine 60mg
Pyrilamine maleate 15mg

purpose

- Pain reliever
- Diuretic
- Antihistamine

Uses

for the temporary relief of these symptoms associated with menstrual periods:

- cramps
- bloating
- waterweight gain
- headache
- backache
- muscle aches
- fatigue

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 softgel in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include: • hives • blisters • rash • skin reddening • facial swelling • asthma (wheezing) • shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- you may get drowsy
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

If pregnant or breast-feeding, ask a health professional before use

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 take more than the recommended dose
- adults and children 12 years and older: take 2 softgel with water
- repeat every 6 hours as needed
- do not exceed 6 softgel per day
- children under 12 years: consult a doctor

store at room temperature.

Inactive ingredients

croscarmellose sodium, D&C red 33 aluminum lake, edible black printing ink, ethyl cellulose, FD&C blue 1 aluminum lake, gelatin, glycerin, hydroxypropyl methylcellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, pregelatinized potato starch, purified water, PVPK-30, sorbitol sorbitan solution, talc, titanium dioxide, triacetin.

<u>ACETAMINOPHEN 500MG, CAFFEINE 60MG, PYRILAMINE MALEATE 15MG SOFTGELATIN</u>		Imprint
<u>CAPSULE</u>		
Each Soft Gelatin Capsule Contains: (Acetaminophen USP 500mg, Caffeine USP 60mg, Pyrilamine Maleate USP 15mg)		
BATCH NO	:	NDC NO : 35916-0710-1
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		
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 : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"</u>		

ACETAMINOPHEN , CAFFEINE AND PYRILAMINE MALEATE

acetaminophen , caffeine and pyrilamine maleate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0710
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
WATER (UNII: 059QF0KO0R)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
D&C RED NO. 33 ALUMINUM LAKE (UNII: L3FT3LUT29)
STARCH, POTATO (UNII: 8I089SAH3T)
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)
GLYCERIN (UNII: PDC6A3C0OX)
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SORBITOL (UNII: 506T60A25R)
SORBITAN (UNII: 6O92ICV9RU)
TALC (UNII: 7SEV7J4R1U)
TRIACETIN (UNII: XHX3C3X673)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POVIDONE K30 (UNII: U725QWY32X)
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)

Product Characteristics

Color	blue (Dark blue and light blue)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0710-1	1500 in 1 BAG; Type 0: Not a Combination Product	12/12/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/12/2025	

Labeler - Softgel Healthcare Pvt Ltd (676666501)