

ACETAMINOPHEN,CAFFEINE AND PYRILAMINE MALEATE-
acetaminophen,caffeine and pyrilamine maleate tablet
APNAR PHARMA LP

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.

Acetaminophen 500mg, Caffeine 60mg, Pyrilamine Maleate 15mg Tablets

Caution: Do not use if imprinted seal under cap is broken or missing

Drug facts

Active Ingredient (in each tablet)

Acetaminophen USP..... 500 mg

Caffeine USP.....60 mg

Pyrilamine Maleate USP.....15 mg

Purpose

Pain reliever/Diuretic/Antihistamine

Use(s)

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

- cramps
- bloating
- water-weight gain
- headache
- backache
- muscle aches
- fatigue

Warnings:

Liver warning:

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

- more than 6 tablets 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 allergy reactions. Symptoms may include:

- Skin reddening
- blisters
- rash
- hives
- 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 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 get worse or lasts more than 3 days

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

Overdose warning

In case of overdose, get medical help or contact a poison control center 1-800-222-1222 right away. Quick medical help attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Directions

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

Other Information

- Store at 15° - 30°C (59° - 86° F).

Inactive Ingredients

pregelatinized starch, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide, talc

Questions or comments?

1-855-642-2594

Manufactured for:

Apnar Pharma LP

CHINO, CA, 91710

Rev.: 05/2022

†This product is not manufactured or distributed by Bayer Healthcare, LLC owner of the registered trademark Midol Complete®

APNAR PHARMA LP

NDC: 24689-121-01

Acetaminophen 500mg, Caffeine 60mg, Pyrilamine Maleate 15mg Tablets - 20's Tablets

Glue Area

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 get worse or lasts more than 10 days
- fever get worse or lasts more than 3 days

If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children.

Overdose Warning

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- do not take more than the recommended dose
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- repeat every 6 hours or as needed
- do not exceed 6 tablets per day
- children under 12 years: consult a doctor

Other information

- Store at 15° - 30°C (59° - 86° F).

Inactive ingredients

Pregelatinized starch, Microcrystalline cellulose, Croscarmellose sodium, Povidone, Colloidal silicon dioxide, Magnesium stearate, Hypromellose, Polyethylene Glycol, Titanium Dioxide, Talc

Questions or comments?

- 1-855-642-2594

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Rev.: 05/2022

NDC 24689-121-01

†compare to MIDOL® COMPLETE active Ingredients.

Maximum Strength

Acetaminophen 500mg, Caffeine 60mg, Pyrilamine Maleate 15mg Tablets

pain reliever/diuretic/antihistamine/
menstrual complete pain relief

- MULTI-SYMPTOM RELIEF Cramps, Bloating, Fatigue, Backache & Headache

20 Tablets



Manufactured by:
Apnar Pharma LP
CHINO, CA, 91710

Caution: Do not use if imprinted seal under cap is broken or missing.

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen USP 500 mg.....Pain reliever
Caffeine USP 60 mg.....Diuretic
Pyrilamine Maleate USP 15mg.....Antihistamine

Use(s) for the temporary relief of these symptoms associated with menstrual periods:

- cramps
- bloating
- water-weight gain
- headache
- backache
- muscle aches
- fatigue

Warnings:

Liver warning:

- This product contains acetaminophen. Severe liver damage may occur if you take more than 6 tablets 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 allergy reactions. Symptoms may include:

- skin reddening
- hives
- facial swelling
- skin redness
- blisters
- rash
- 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 non prescription). 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.

Peel here for more drug facts



Unvarnished Area/ Coding Area
(12 x 50 mm)

APNAR PHARMA LP

NDC: 24689-121-02

Acetaminophen 500mg, Caffeine 60mg, Pyrilamine Maleate 15mg Tablets - 500's Tablets

NDC 24689-121-02

†compare to MIDOL® COMPLETE

active ingredients.

Maximum Strength

Acetaminophen

500mg,

Caffeine 60mg,

Pyrilamine

Maleate 15mg

Tablets

pain reliever/diuretic/antihistamine/
menstrual complete pain relief

• MULTI-SYMPTOM RELIEF

Cramps, Bloating, Fatigue, Backache
& Headache

500 Tablets

APNAR

PHARMA

Manufactured for:
Apnar Pharma LP
CHINO, CA, 91710

Caution: Do not use if imprinted seal under cap is broken or missing.

Purpose

Active ingredient (in each tablet)

Acetaminophen USP 500 mg.....Pain reliever

Caffeine USP 60 mg.....Diuretic

Pyrilamine Maleate USP 15mg.....Antihistamine

Use(s) for the temporary relief of these symptoms associated with menstrual periods:

• cramps

• bloating

• backache

• muscle aches

• water-weight gain

• headache

• fatigue

Warnings:

• **Important:** This product contains acetaminophen. Severe liver damage may occur if you take more than 6 tablets 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 allergy reactions. Symptoms may include:

• skin reddening

• blisters

• rash

• hives

• 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

• avoid activities, and machinery that require alertness or coordination

• because of the caffeine, drowsiness may be counteracted by increased alertness

• 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

• 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 care professional before use. Keep out of reach of children.

Warnings:

• In case of overdose, get medical help or contact a poison control center 1-800-222-1222 right away. Quick 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 of age or older: take 2 tablets with water • repeat every 6 hours or as needed • do not exceed 6 tablets per day • children under 12 years: consult a doctor

Other information

• Store at 15° - 30°C (59° - 86° F).

Inactive ingredients

Prepregelized starch, Microcrystalline cellulose, Croscarmellose sodium, Povidone, Colloidal silicon dioxide, Magnesium stearate, Hypromellose, Polyethylene Glycol, Titanium Dioxide, Talc

Questions or comments?

• 1-855-642-2594

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Unvarnished Area/Coding Area

(35 x 12 mm)

Rev.: 05/2022

N 3 2 4 6 8 9 1 1 2 1 0 2 1 4

ACETAMINOPHEN,CAFFEINE AND PYRILAMINE MALEATE

acetaminophen,caffeine and pyrilamine maleate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-121
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
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	white (white to off-white)	Score	no score
Shape	OVAL	Size	18mm

Flavor		Imprint Code	LT16
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-121-01	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2022	
2	NDC:24689-121-02	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/05/2022	

Labeler - APNAR PHARMA LP (079568229)

Establishment			
Name	Address	ID/FEI	Business Operations
Apnar Pharma Private Limited		876730408	analysis(24689-121) , manufacture(24689-121)

Establishment			
Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	pack(24689-121) , label(24689-121)

Revised: 1/2023

APNAR PHARMA LP