

**ACETAMINOPHEN 500MG CAFFEINE 60MG PYRILAMINE MALEATE 15MG-
acetaminophen 500mg caffeine 60mg pyrilamine maleate 15mg tablet
OPMX LLC**

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.

Bus compositum

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

Acetaminophen 500mg

Caffeine 60mg

Pyrilamine maleate 15mg

ammonium hydroxide, croscarmellose sodium, D&C red No. 33 aluminum lake, ethyl cellulose, FD&C blue No. 1 aluminum lake, gelatin, glycerin, hypromellose, iron oxide black, light mineral oil, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch, propylene glycol, shellac glaze, sorbitol sorbitan, talc, titanium dioxide, triacetin

- Do not take more than the recommended dose
- Adults and children 12 years and over: take 2 gelcaps with water, repeat every 6 hours, as needed; do not exceed 6 gelcaps per day
- Children under 12 years: consult a doctor

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

Cramps, bloating water-weight gain, headache, backache, muscle aches, fatigue.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 6 gelcaps in 24 hours, which is the maximum daily amount for this product, with other drugs contains acetaminophen, 3 or more alcoholic drinks every day while using this product.

Allergy alert: Acetaminophen may cause severe skin reactions or severe allergic 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, 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 for more than 10 days, fever gets worse or lasts for 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Pain reliever

Nighttime sleep-aid

Store at room temperature between 20-25 °C (68-77 °F)

ACETAMINOPHEN 500MG CAFFEINE 60MG PYRILAMINE MALEATE 15MG

27.1 mm

71.6 mm

77.6 mm

NDC 69729-145-22



Buscompositum

Pain Reliever

- Cramps / Cólicos • Bloating / Hinchazón
- Fatigue / Fatiga • Headache / Dolor de Cabeza
- Backache / Dolor de Espalda

12 Gelcaps

Drug Facts (continued)

Active Ingredients (in each gelcap)

Acetaminophen 500 mg Pain Reliever
Caffeine 60 mg
Pyrilamine Maleate 15 mg Antihistamine

Uses

For the temporary relief of these symptoms associated with menstrual periods: cramps ■ bloating ■ water-weight gain ■ headache ■ backache ■ muscle aches ■ fatigue

Drug Facts (continued)

Warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 6 gelcaps in 24 hours, which is the maximum daily amount for this product. Do not take with other drugs containing acetaminophen. Do not take 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: skin redness ■ hives ■ rash ■ blisters (bubbling) ■ shock 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

Drug Facts (continued)

Warnings: This product contains acetaminophen. Taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers ■ you may get drowsy ■ avoid alcoholic drinks ■ excitability may occur, especially in children ■ alcohol, sedatives, and tranquilizers may increase drowsiness. **Allergy alert:** acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include: skin redness ■ hives ■ rash ■ blisters (bubbling) ■ shock 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

Drug Facts (continued)

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.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Other Information

Store at room temperature 68-77°F (20-25°C).
FDC Blue No. 1 aluminum lake gelcaps, pyrilamine hydrochloride, croscarmellose sodium, D&G red No. 33 aluminum lake ethylcellulose, cellulose, polydine, preblended starch, pyrene glycol, stearic acid, glycerol, croscarmellose sodium, D&G red No. 33 aluminum lake, microcrystalline cellulose, polydine, preblended starch, pyrene glycol, stearic acid, glycerol, croscarmellose sodium, D&G red No. 33 aluminum lake, ethylcellulose.

Inactive Ingredients

ammonium hydroxide, croscarmellose sodium, D&G red No. 33 aluminum lake, ethylcellulose, cellulose, polydine, preblended starch, pyrene glycol, stearic acid, glycerol, croscarmellose sodium, D&G red No. 33 aluminum lake, ethylcellulose.

Questions or comments? 619-600-5632

READ & KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Lot. No.:
Exp. Date:

8 56828 00899 1

1

Exclusively distributed by:

Made for:




Chula Vista, CA 91910
Phone: 619-600-5632

TAMPER EVIDENT: This product contains a tamper-evident cap. If the cap is broken or shows signs of tampering, do not use.




acetaminophen 500mg caffeine 60mg pyrillamine maleate 15mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-145
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POVIDONE (UNII: FZ989GH94E)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	blue (DARK BLUE and LIGHT BLUE)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	S79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-145-22	12 in 1 PACKAGE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2020	

Labeler - OPMX LLC (029918743)

Revised: 11/2020

OPMX LLC