

**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.*

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**Buscolicos**

**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)



## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-144
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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

<b>Ingredient Name</b>	<b>Strength</b>
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

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-144-22	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