

**BUSCAPINA- acetaminophen, caffeine, pyrilamine maleate tablet, coated  
OPMX LLC**

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**Buscapina**

***Drug Facts***

**Active ingredients**

**Purpose**

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***Active Ingredients (in each caplet)***

Acetaminophen 500mg  
Caffeine 60mg  
Pyrilamine maleate 15mg

***Purpose***

Pain reliever  
Diuretic  
Antihistamine

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***Uses***

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 caplets 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: •

- 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 appear
- 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.**

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.

### **Directions**

- do not exceed recommended dosage

- adults and children 12 years and over: take 2 caplets with water. Repeat every 6 hours as needed. Do not exceed 6 caplets per day.
  - children under 12 years: consult a doctor

### **Other information**

- store at room temperature 68-77°F (20-25°C)
- TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING

### **Inactive ingredients**

colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, pvp K-30, sodium starch glycolate, stearic acid, talc, titanium dioxide

### **Questions or comments?**

Call toll free 619-600-5632

Monday through Friday 9AM - 5PM EST

### **Buscapina 6 caplets**

Buscapina

Acetaminophen, Caffeine, Pyrilamine Maleate Tablets

NDC 69729-132-06

- Cramps
- Bloating
- Fatigue
- Heacache
- Backache

6 Caplets

3 packs of 2 Caplets



NDC 69729-132-06

# Buscapina

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

**Multi-Symptom  
Pain Relief**

- **Cramps**
- **Bloating**
- **Fatigue**
- **Headache**
- **Backache**

**6 Caplets**  
3 packs of 2 Caplets



**Buscapina**

INSTRUCCIONES EN ESPAÑOL EN EL INTERIOR DE LA CAJA.

Exclusively distributed by:



Made for:



REV. 08/2023 ITEM # RRX1129

EXP. DATE

LOT

**Uses** 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 caplets 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: ■ skin redness ■ hives ■ rash ■ 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 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 appear ■ 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.** 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.

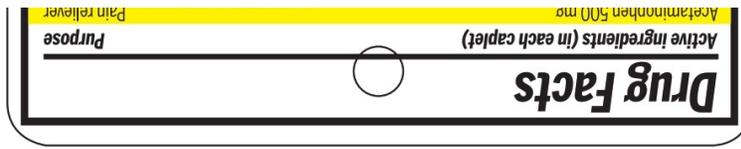
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**Questions or comments?** Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

Pyrilamine maleate 15 mg  
Caffeine 60 mg  
.....Antihistamine  
.....Diluent



## BUSCAPINA

acetaminophen, caffeine, pyrilamine maleate tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-132
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	V1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-132-06	3 in 1 CARTON	09/04/2023	

1	2 in 1 PACKET; Type 0: Not a Combination Product		
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/04/2023	

**Labeler -** OPMX LLC (029918743)

### Establishment

Name	Address	ID/FEI	Business Operations
Vovantis Laboratories Private Limited		650502151	manufacture(69729-132)

Revised: 12/2024

OPMX LLC