

BUSCAPINA- acetaminophen, caffeine, pyrilamine maleate tablet, coated 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.

Buscapina

Drug Facts

Active ingredients

Purpose

Active Ingredients (in each caplet)

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
- 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
- Headache
- Backache

6 Caplets

3 packs of 2 Caplets



Fatiga

Buscapina

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:

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



Made for:

RRX
San Diego, CA

Warnings: This product contains acetaminophen. Do not take more than 6 caplets in 24 hours, which is the maximum daily amount for this product. If you take 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 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.

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Inactive ingredients: colloidal silicon dioxide, hydroxypropyl methyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, pvp k-30, sodium starch glycolate, stearic acid, talc, titanium dioxide

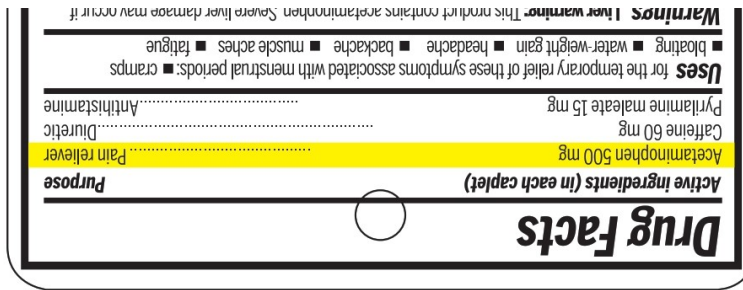
Questions or comments? Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

REV. 08.2023 ITEM # RRX1129

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LOT

EXP. DATE



BUSCAPINA

acetaminophen, caffeine, pyrilamine maleate tablet, coated

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

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

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/04/2023	

Labeler - OPMX LLC (029918743)

Establishment

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

Revised: 9/2023

OPMX LLC