

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

Buscapina

Active Ingredients (in each caplet)

Acetaminophen 500mg, Caffeine 60mg, and Ppyrilamine maleate 15mg

Purpose

Pain Reliever, Diuretic, Antihistamine, Multi-Symptom Relief

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 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 warning: 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 (1-800-222-1222) 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 tablets with water. Repeat every 6 hours, as needed. Do not exceed 6 tablets per day
- Children under 12 years: Consult a doctor

Other Information

- Store at room temperature

- TAMPER EVIDENT; DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients

- Colloidal silicon dioxide
- Hypromellose
- Magnesium stearate
- Microcrystalline cellulose
- Polyethylene glycol
- Polyvinyl pyrrolidone
- Pregelatinized starch
- Titanium dioxide
- Talc

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM or www.healthlifeofusa.com

Buscapina

Acetaminophen 500mg

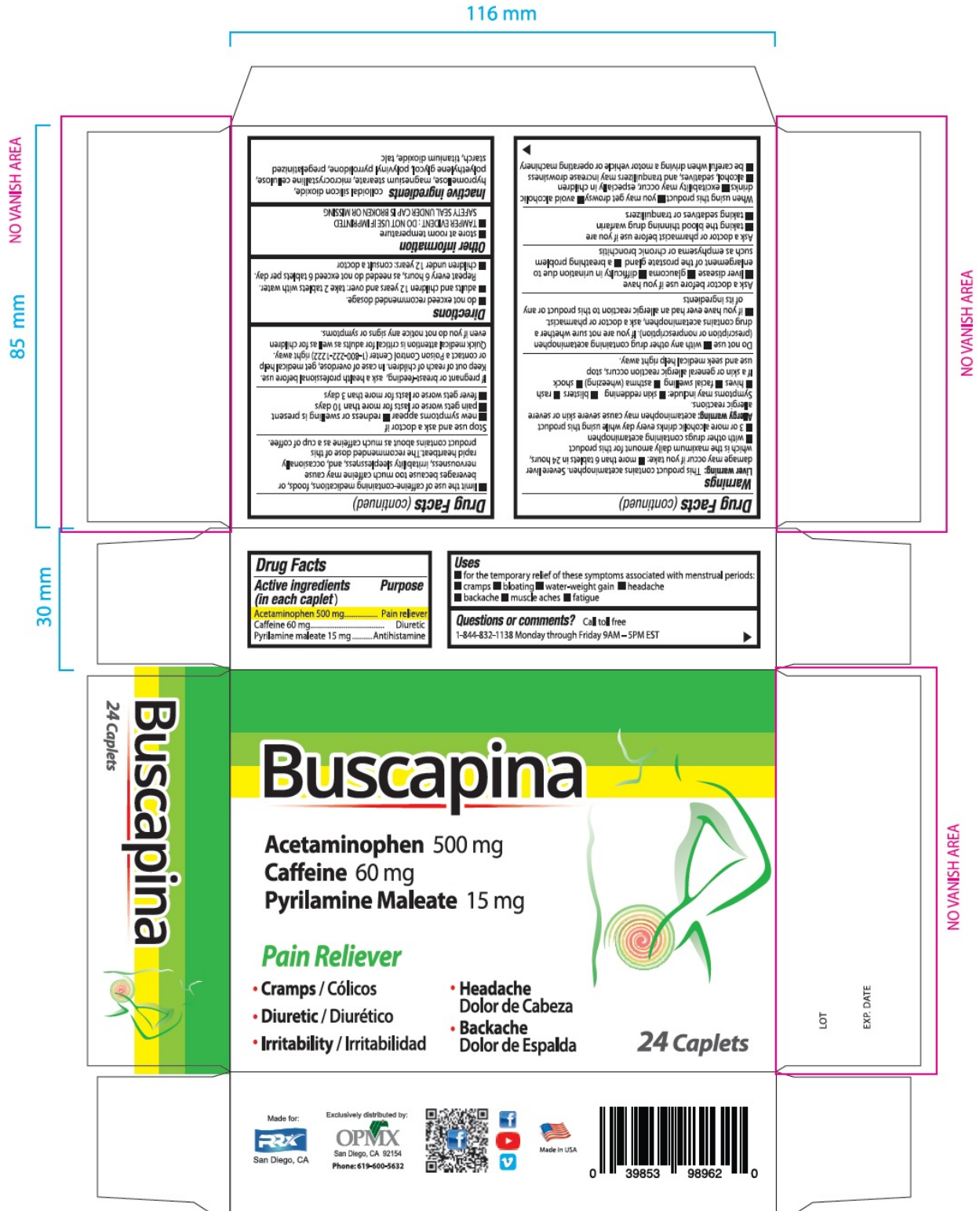
Caffeine 60mg

Pyrilamine maleate 15mg

24 Caplets Distributed By:

OPMX

San Diego, CA, 92154



BUSCAPINA

acetaminophen, caffeine, pyrilamine maleate tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	17mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-130-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/05/2018	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Limited		915664486	manufacture(69729-130)