MENSTRUAL RELIEF MAXIMUM STRENGTH MULTI SYMPTOM- acetaminophen, pamabrom, pyrilamine maleate tablet, film coated Cardinal Health 110, LLC. DBA Leader

Leader 44-679

Active ingredients (in each caplet)

Acetaminophen 500 mg Pamabrom 25 mg Pyrilamine maleate 15 mg

Purpose

Pain reliever Diuretic Antihistamine

Uses

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

- headache
- bloating
- cramps
- backache
- muscular aches
- irritability
- water-weight gain

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin 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

- difficulty in urination due to enlargement of the prostate gland
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness may occur
- avoid alcoholic beverages
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- do not take more than directed
- adults and children 12 years and over:
 - take 2 caplets with water every 6 hours as needed
 - do not exceed 6 caplets in a 24 hour period or as directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, shellac wax, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

LEADER™

NDC 70000-0145-1

Maximum Strength Multi-Symptom

Menstrual Relief

Acetaminophen | Pamabrom | Pyrilamine maleate

Pain Reliever | Diuretic | Antihistamine

Relieves:

Cramps, Bloating, Irritability, Headache and Backache

20 CAPLETS

ACTUAL SIZE

COMPARE TO MAXIMUM STRENGTH PAMPRIN® MULTI-SYMPTOM active ingredients*

100% Money Back Guarantee

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

*This product is not manufactured or distributed by Focus Consumer Healthcare, LLC, owner of the registered trademark Maximum Strength Pamprin® Multi-Symptom.

50844 REV0718A67909

CardinalHealth™

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100% Money Back Guarantee Return to place of purchase.



acetaminophen, pamabrom, pyrilamine maleate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0145
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		
PAMABROM (UNII: UA8U0KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6)	PAMABROM	25 mg		
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SHELLAC (UNII: 46N107B710)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	purple	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	44;679	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0145-1	1 in 1 CARTON	01/13/2015	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/13/2015	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0145)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(70000-0145)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0145)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(70000-0145)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0145)

Revised: 9/2023 Cardinal Health 110, LLC. DBA Leader