MENSTRUAL RELIEF MAXIMUM STRENGTH- acetaminophen, pamabrom, pyrilamine maleate tablet, film coated Topco Associates, 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.

TopCare 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:

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

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?

Principal Display Panel

TopCare

health®

NDC 36800-979-10

COMPARE TO MAXIMUM STRENGTH PAMPRIN® MULTI-SYMPTOM ACTIVE INGREDIENTS*

MAXIMUM STRENGTH

Menstrual Relief

ACETAMINOPHEN - PAIN RELIEVER • PAMABROM - DIURETIC

• PYRILAMINE MALEATE - ANTIHISTAMINE

MULTI-SYMPTOM RELIEF OF: Cramps

• Bloating • Irritability • Headache • Backache

OUR PHARMACISTS RECOMMEND

40 CAPLETS

actual

size

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA0220 QUESTIONS? 1-888-423-0139 topcare@topco.comwww.topcarebrand.com

QUALITY GUARANTEED

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

50844 REV0718A67910



TopCare 44-679

MENSTRUAL RELIEF MAXIMUM STRENGTH

acetaminophen, pamabrom, pyrilamine maleate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-979
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAMABROM (UNII: UA8 U0 KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6)	PAMABROM	25 mg
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CROSPO VIDO NE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989 GH9 4E)	
SHELLAC (UNII: 46 N10 7B710)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:36800-979-	1 in 1 CARTON	0 1/13/20 15			
1	40 in 1 BOTTLE, PLASTIC; 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	0 1/13/20 15			

Labeler - Topco Associates, LLC (006935977)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(36800-979)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(36800-979)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(36800-979)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(36800-979)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(36800-979)

Revised: 5/2020 Topco Associates, LLC