PAMPRIN MULTI-SYMPTOM MAXIMUM STRENGTH- acetaminophen, pamabrom, pyrilamine maleate tablet Focus Consumer Healthcare, 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.

Pamprin MultiSymptom

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg Pamabrom 25 mg Pyrilamine maleate 15 mg

Purposes

Pain reliever Diuretic Antihistamine

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

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

Allergy warning: 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.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 8 caplets in 24 hours, which is the maximum daily amount • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product

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.

Ask a doctor before use if you have • liver disease • glaucoma • a breathing problem such as emphysema or chronic bronchitis • difficulty in urination due to enlargement of the prostate gland

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 beverages • alcohol, sedatives and tranquilizers may increase drowsiness • use caution when driving or operating machinery • excitability may occur, especially in children

Stop use and ask a doctor if

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

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

adults and children 12 years and over:

- take 2 caplets with water every 6 hours as needed
- do not exceed 8 caplets in a 24 hour period or as directed by a doctor
- do not use more than directed (see warnings)

children under 12 years: ask a doctor

blue 2, candelilla wax, corn starch, ethylparaben, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylparaben, red 40, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or Comments?

www.pamprin.com

IF IMPRINTED INNER SEAL ON BOTTLE IS BROKEN OR MISSING, DO NOT USE.

Easy-open bottle with child-resisitant packaging. Purchase only if carton end flaps are sealed.

Distributed by:

Focus Consumer Healthcare, LLC

801 Broad Street, Chattanooga, TN 37402

Made in Canada

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www.pamprin.com

Maximum Strength

Pamprin Multi-Symptom

for complete Relief of • Cramps • Headache • Backache • Irritability • Bloating

Mentrual Pain Relief

Aspirin-free and Caffeine-free with Acetaminophen, Pamabrom and Pyrilamine Maleate

20 Caplets





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Drug Facts (continued) Warnings

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acetaminophen, pamabrom, pyrilamine maleate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71687-3003
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
PAMABROM (UNII: UA8 U0 KJM72) (BROMOTHEO PHYLLINE - UNII: FZG8 7 K1 MQ6)	PAMABROM	25 mg
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII:36209 ITL9 D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	Strength
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CANDELILLA WAX (UNII: WL0328HX19)	
STARCH, CORN (UNII: O8232NY3SJ)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	purple	Score	no score	
Shape	CAPSULE	Size	18 mm	
Flavor		Imprint Code	P	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:71687-3003	1 in 1 CARTON	06/01/2016		
1	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
NDC:71687-3003	1 in 1 CARTON	06/01/2016		
2	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			



Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart34306/01/2016

Labeler - Focus Consumer Healthcare, LLC (080743737)

Revised: 6/2020 Focus Consumer Healthcare, LLC