FEMADRINE- acetaminophen, pamabrom tablet Afassco Inc.

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.

Drug Facts

Acetaminophen 325mg

Pamabrom 25mg

Pain reliever, Diuretic

Uses: For the relief of:

- cramps bloating water-weight gain
- headaches backaches muscular aches and pains

Warnings:

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: • more than 8 tablets in 24 hours

- with any other drugs containing acetaminophen (prescription or non-prescription).
- 3 or more alcoholic drinks a while using this product.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Keep out of reach of children.

If pregnant or breast-feeding, ask a health professional before use.

In case of 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 use more than directed.

Adults and children: (12 years and older) Take 2 tablets with water. Repeat every 4 hours, as needed, not to exceed 8 tablets in any 24 hour period.

Children under 12 years of age: Consult a doctor.

SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION



2 Tablets

Active Ingredients (In Each Tablet)

Purposes

Acetaminophen 325 mg....Pain Reliever Pamabrom 25 mg.....Diuretic

Uses: For the relief of:

- cramps bloating water-weight gain
- headaches backaches muscular aches and pains

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• with any other drugs containing acetaminophen (prescription or non-prescription).

Questions? Contact Afassco Minden, NV 89423 Store at room temperature Tamper evident: Do not use packet if torn or cut.

Warnings (continued)

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FEMADRINE

acetaminophen, pamabrom tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-0700
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325	
PAMABROM (UNII: UA8 U0 KJM72) (BROMOTHEO PHYLLINE - UNII: FZG8 7K1MQ6)	PAMABROM	25	

Inactive Ingredients		
Ingredient Name	Strength	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
PO VIDO NE (UNII: FZ989 GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Product Characteristics			
Color	white (with red and green crystals)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR7
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51532-0700-2	2 in 1 PACKET; Type 0: Not a Combination Product	10/25/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/25/2016	

Labeler - Afassco Inc. (609982723)

Revised: 11/2016 Afassco Inc.