

FLO PMS COMPLETE- acetaminophen, caffeine, pyrilamine maleate tablet
O Positiv, Inc.

FLO® PMS COMPLETE

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg
Caffeine 60 mg
Pyrilamine maleate 15 mg

Purpose

Pain reliever
Diuretic
Antihistamine

Uses

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

- bloating • headache • muscle aches
- cramps • backache • fatigue
- 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 • if you have ever had an allergic reaction to this product or any of its ingredients

- 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

- difficulty in urination due to enlargement of the prostate gland • liver disease • glaucoma

- 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

- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness • you may get drowsy
- limit the use of caffeine-containing medications, foods, or beverages while taking this product 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.
- avoid alcoholic beverages

Stop use and ask a doctor if • new symptoms occur • redness or swelling is present

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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 the recommended dose

- adults and children 12 years and over:
 - take 2 caplets with water
 - repeat every 6 hours, as needed
 - do not exceed 6 caplets per day
- children under 12 years: ask a doctor

Other information

• TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

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

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Maximum Strength

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

OPOSITIV.COM

Distributed By: O Positiv, Inc.

11740 San Vicente Blvd Los Angeles, CA 90049

Packaging

INNER PACKAGE LABEL

FLO Each caplet contains:
Acetaminophen 500 mg,
Caffeine 60 mg,
Pyrilamine maleate 15 mg

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

Fold along perforations; peel back at arrows; push through foil.

Dist. By O Positiv, Los Angeles, CA 90049

LOT# XXXXXX EXP. XXXX

OUTER PACKAGE LABEL

<p>Directions</p> <ul style="list-style-type: none"> • take 2 caplets with water • adults and children 12 years and over: • do not take more than the recommended dose <p>Drug Facts (continued)</p> <p>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.</p> <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • repeat every 6 hours, as needed • do not exceed 6 caplets per day • children under 12 years: ask a doctor <p>Other information • TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN</p> <ul style="list-style-type: none"> • see end flap for expiration date and lot number 	<p>TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING</p> <p>8 60008 75121 8</p> <p>armish area xp. date</p>
<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) <p>Inactive ingredients corn starch, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide</p> <p>Questions or comments? 1-800-426-9391</p>	<p>Do not use • If you have ever had an allergic reaction to this product or any of its ingredients (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • difficulty in urination due to enlargement of the prostate gland • liver disease • glaucoma • a breathing problem such as emphysema or chronic bronchitis <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> • taking the blood thinning drug warfarin • taking sedatives or tranquilizers <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison professional before use.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Stop use and ask a doctor if • new symptoms occur • redness or swelling is present</p> <ul style="list-style-type: none"> • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • These could be signs of a serious condition. <p>Use and ask a doctor if • new symptoms occur • redness or swelling is present</p> <ul style="list-style-type: none"> • avoid alcoholic beverages • caffeine as a cup of coffee. • 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. • limit the use of caffeine-containing medications, foods, or beverages while taking this product • drowsiness • you may get drowsy • alcohol, sedatives, and tranquilizers may increase

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Drug Facts (continued)
 • 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

When using this product
 • excitability may occur, especially in children
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crospovidone,
 polydextrose,
 titanium dioxide,
 97-867)

Drug Facts
 KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active Ingredients (in each caplet)
 Acetaminophen 500 mg..... Pain reliever
 Caffeine 60 mg..... Diuretic
 Pyrilamine maleate 15 mg..... Antihistamine

Purpose
 symptoms associated with menstrual periods:

Warnings
 • water-weight gain
 • cramps
 • bloating
 • headache
 • muscle aches

Uses for the temporary relief of these

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



PMS COMPLETE

Acetaminophen • Pain Reliever •
 Caffeine • Diuretic • Pyrilamine Maleate • Antihistamine

Multi-symptom relief from:
 Cramps • Bloating • Fatigue
 Headache • Backache

24 Caplets



Maximum Strength **Actual Size**

DRUG FACTS TABLE

Drug Facts		Drug Facts (continued)	
Active ingredients (in each caplet)	Purpose	symptoms associated with menstrual periods:	
Acetaminophen 500 mg.....	Pain reliever	• bloating	• headache
Caffeine 60 mg.....	Diuretic	• cramps	• backache
Pyrilamine maleate 15 mg.....	Antihistamine	• water-weight gain	• muscle aches
Uses	for the temporary relief of these	Warnings	
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Drug Facts (continued)	Drug Facts (continued)
<ul style="list-style-type: none"> • 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> • skin reddening • blisters • rash <p>If a skin reaction occurs, stop use and seek</p>	<p>When using this product</p> <ul style="list-style-type: none"> • excitability may occur, especially in children • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives, and tranquilizers may increase drowsiness • you may get drowsy • limit the use of caffeine-containing medications, foods, or beverages while taking this product

medical help right away.

Do not use

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- new symptoms occur
 - redness or swelling is present
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Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison

Drug Facts (continued)

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.

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Drug Facts (continued)

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Questions or comments? 1-800-426-9391

FLO PMS COMPLETE

acetaminophen, caffeine, pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83049-489
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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	FLO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83049-489-08	3 in 1 CARTON	12/05/2022	
1		8 in 1 BLISTER PACK; 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	12/05/2022	

Labeler - O Positiv, Inc. (107922667)

Revised: 10/2023

O Positiv, Inc.