

MENSTRUAL COMPLETE GELCAPS- acetaminophen, caffeine, pyrilamine maleate tablet, coated
Dolgenercorp 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.

Menstrual Complete

Drug Facts

Active ingredients (in each gelcap)

Acetaminophen 500 mg
Caffeine 60 mg
Pyrilamine maleate 15 mg

Purposes

Pain reliever
Diuretic
Antihistamine

Uses

for the temporary relief of these symptoms associated with menstrual periods: • cramps • bloating • water-weight gain • headache • backache • muscle aches • fatigue

Warnings

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

- more than 6 gelcaps in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include: • hives • blisters • rash • skin reddening • facial swelling • asthma (wheezing) • shock

If a skin or general allergic 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

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

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

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

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

Keep out of reach of children.

Overdose warning: 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 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 older: take 2 gelcaps with water • repeat every 6 hours as needed • do not exceed 6 gelcaps per day
- children under 12 years: consult a doctor

Other information

each gelcap contains: **sodium 3 mg** (very low sodium)

Store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients

croscarmellose sodium, D&C red #33 aluminum lake, edible black printing ink, ethyl cellulose, FD&C blue #1 aluminum lake, gelatin, glycerin, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone K30, pregelatinized starch, purified water, sorbitol sorbitan solution, talc, titanium dioxide, triacetin

Questions or comments?

1-888-577-8033 Monday - Friday 8am - 4pm EST

Compare to active ingredients of Midol® Complete*

DG™ health

Multi-Symptom Relief of:

- Cramps
- Bloating
- Fatigue
- Backache
- Headache

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Midol®.

DISTRIBUTED BY: OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

PRODUCT OF UNITED ARAB EMIRATES

Packaging

DRUG FACTS TABLE



Drug Facts (continued)

Other information Store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients croscarmellose sodium, D&C red #33 aluminum lake, edible black printing ink, ethyl cellulose, FD&C blue #1 aluminum lake, gelatin, glycerin, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone K30, pregelatinized starch, purified water, sorbitol sorbitan solution, talc, titanium dioxide, triacetin

Questions or comments? 1-888-577-8033 Monday - Friday 8am - 4pm EST

Menstrual Complete

Acetaminophen, 500 mg
Caffeine, 60 mg
Pyrilamine Maleate, 15 mg
Pain Reliever/Diuretic/Antihistamine

Multi-Symptom Relief of:

- Cramps
- Bloating
- Fatigue
- Backache
- Headache

24 Gelscaps

Actual Gelscap Size

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

Drug Facts

Active ingredients (in each gelcap)

Acetaminophen 500 mg..... Pain reliever
Caffeine 60 mg..... Diuretic
Pyrilamine maleate 15 mg..... Antihistamine

Purposes

Uses for the temporary relief of these symptoms associated with menstrual periods: ■ cramps ■ bloating ■ water-weight gain ■ headache ■ backache ■ muscle aches ■ fatigue

Drug Facts (continued)

Warnings

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

- more than 6 gelscaps in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include: ■ hives ■ blisters ■ rash ■ skin reddening ■ facial swelling ■ asthma (wheezing) ■ shock

If a skin or general allergic 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

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

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

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

Overdose warning: 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 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 older: take 2 gelscaps with water ■ repeat every 6 hours as needed ■ do not exceed 6 gelscaps per day
- children under 12 years: consult a doctor

Other information

each gelcap contains: **sodium 3mg** (very low sodium)

Drug Facts (continued)

Other information Store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients croscarmellose sodium, D&C red #33 aluminum lake, edible black printing ink, ethyl cellulose, FD&C blue #1 aluminum lake, gelatin, glycerin, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone K30, pregelatinized starch, purified water, sorbitol sorbitan solution, talc, titanium dioxide, triacetin

Questions or comments? 1-888-577-8033 Monday - Friday 8am - 4pm EST

MENSTRUUAL COMPLETE GELCAPS acetaminophen, caffeine, pyrilamine maleate tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-960
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, POTATO (UNII: 8I089SAH3T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	Score	no score
Shape	RECTANGLE	Size	18mm
Flavor		Imprint Code	S79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-960-24	3 in 1 CARTON	01/25/2023	
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 not final	part343	01/25/2023	

Labeler - Dolgencorp Inc (068331990)

