

**DOLEX FEM- acetaminophen, caffeine, pyrilamine maleate tablet, coated
Pharmadel 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.

Dolex Fem (Health Pharma)

Drug Facts

Active ingredients & Purposes

<u>Active ingredients (in each caplet)</u>	<u>Purposes</u>
Acetaminophen 500mg.....	Pain reliever
Caffeine 60mg	Diuretic
Pyrilamine maleate 15mg.....	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 caplets 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:

- skin reddening
- blisters
- rash

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Caffeine warning: 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 because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

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.
- for more than 10 days for pain unless directed by a doctor
- if allergic to any of the ingredients in this product

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

- may cause excitability in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain persist or gets worse

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of an 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 exceed recommended dose**
- take every **6 hours. Do not exceed 6 caplets** in a 24-hour period
 - adults and children 12 years of age and over: take two (2) tablets, every 6 hours
 - children under 12 years of age: **do not use**

Other information

- Store at room temperature 77-86°F (25-30°C)

Inactive ingredients

corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone k30, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-866-359-3478 (M-F) 9AM - 5PM or www.pharmadel.com

*This product is not manufactured or distributed by Bayer Healthcare LLC owner of the registered trademark Midol[®] Complete.

Prinicpal Display Panel

Compare to Midol[®] Complete active ingredients*

Dolex Fem

Menstrual Complete

Acetaminophen, Caffeine, Pyrilamine Maleate

NDC 55758-326-25

NDC 55758-326-25

DOLEX[®]
Máxima potencia
Maximum Strength

Fem

Alivio de los dolores menstruales
Menstrual Pain Relief

- Calambres / Cramps
- Hinchazón / Swelling
- Fatiga / fatigue

Acetaminofén, Caffeína y Maleato de Pirilamina
Acetaminophen, Caffeine and Pyrilamine Maleate

Compare to Midol[®] Complete active ingredients*
Se compara con los ingredientes activos de Midol[®] Completo*

24 | caplets
capletas

NDC 55758-326-02

NDC 55758-326-02 Contains 2 Caplets

DOLEX[®] Fem

Menstrual Pain Relief

Acetaminophen, Caffeine and Pyrilamine Maleate

Active Ingredients (in each caplet) **Purposes**

Acetaminophen 500mg Pain reliever

Caffeine 60mg Diuretic

Pyrilamine maleate 15mg 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 caplets 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 reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away. Caffeine warning: 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 because ▶

too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat. Do not use ■ with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ for more than 10 days for pain unless directed by a doctor ■ if allergic to any of the ingredients in this product. Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty urinating 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 ■ may cause excitability in children ■ alcohol, sodas, and tranquilizers may increase drowsiness ■ avoid alcoholic beverages while taking this product ■ use caution when driving a motor vehicle or operating machinery. Stop use and ask a doctor if ■ symptoms do not improve ■ new symptoms occur ■ pain persist or gets worse. If pregnant or breast-feeding, ask a health professional before use. **KEEP OUT OF REACH OF CHILDREN.** In case of an 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 exceed recommended dose ■ take every 6 hours; do not exceed 6 caplets in a 24-hour period ■ adults and children 12 years of age and over: take two (2) caplets, every 6 hours ■ children under 12 years of age: do not use. **Other information** ■ store at room temperature 77-86°F (25-30°C). **Inactive ingredients** corn starch, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydione K30, silicon dioxide, sodium starch glycolate, stearic acid, titanium dioxide

*This product is not manufactured or distributed by Bayer Medicines LLC owner of the registered trademark Miltal® Complete.



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Distributed by PHARMADEL LLC
 New Castle, DE, 19720
 +1-888-368-3478
 www.pharmadel.com

DO NOT USE IF
 PACKET IS OPEN
 OR TORN.

NDC 55758-326-50

NDC 55758-326-50

DOLEX[®] Fem

Menstrual Pain Relief

Alivio de los dolores menstruales

- + Cramps
- + Swelling
- + Fatigue

- + Calambres
- + Hinchazón
- + Fatiga



MAX STRENGTH • FUERZA MÁXIMA

• 2 Caplets per packet:
 Each Caplet contains:
 Acetaminophen 500mg,
 Caffeine 60 mg and Pyrilamine Maleate 15 mg

• 2 Caplets por sobrete:
 Cada Capleta contiene:
 Acetaminofén 500mg,
 Cafeína 60 mg y Maleato de Pirilamina 15 mg

25 packets x 2 caplets each
 25 sobres x 2 capletas en cada uno

DOLEX FEM

acetaminophen, caffeine, pyrilamine maleate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-326
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	HH7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-326-25	1 in 1 CARTON	10/01/2020	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55758-326-50	25 in 1 BOX	04/07/2023	
2	NDC:55758-326-02	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:55758-326-02	2 in 1 PACKET; Type 0: Not a Combination Product	04/07/2023	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/01/2020	

Labeler - Pharmadel LLC (030129680)

Revised: 4/2023

Pharmadel LLC