# MAXIMUM STRENGTH MENSTRUAL RELIEF- acetaminophen, caffeine and pyrilamine maleate capsule

## Safeway

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.

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**Safeway 44-390** 

## Active ingredients (in each caplet)

Acetaminophen 500 mg Caffeine 60 mg Pyrilamine maleate 15 mg

## **Purpose**

Pain reliever Stimulant Diuretic

#### Uses

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

## **Warnings**

**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 ammount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinnks 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

- difficulty in urination due to enlargement of the prostate gland
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

## 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
- be careful when driving a motor vehicle or operating machinery
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- 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.

## Stop use and ask a doctor if

- new symptoms appear
- redness or swelling is present
- pain gets worse or lasts more than 10 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.

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

do not take more than the recommended dose

## (see Overdose warning)

- adults and children 12 years and older: take 2 caplets with water. Repeat every 6 hours, as needed.
  Do not exceed 8 caplets in 24 hours.
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

#### Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## **Inactive ingredients**

corn starch, croscarmellose sodium, crospovidone, hypromellose, magneium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silica gel, stearic acid, titanium dioxide, triacetin

#### Questions or comments?

1-888-309-9030

#### **Principal Display Panel**

NDC 21130-390-10

# Compare to Model® Complete active ingredient†

Maximum Strength

**Menstrual Relief** 

## Acetaminophen,

Caffeine, Pyrilamine maleate

Pain Reliever / Stimulant / Diuretic

- Cramps
- Bloating
- Fatigue
- Backache
- Headache

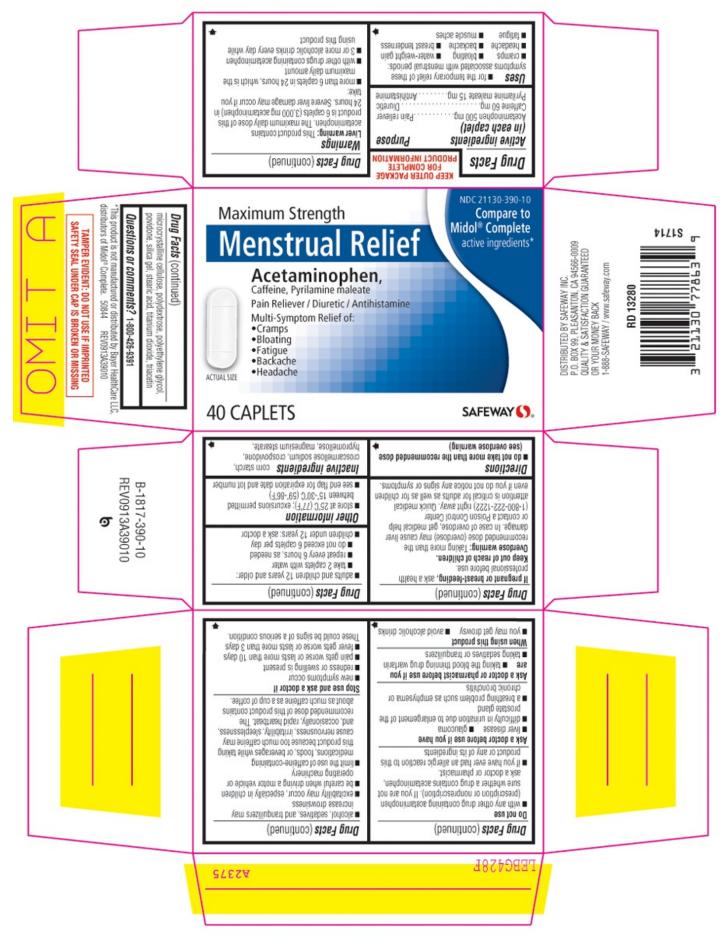
# **40** TABLETS

#### **SAFEWAY**<sub>TM</sub>

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Midol® Complete.

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



# MAXIMUM STRENGTH MENSTRUAL RELIEF

acetaminophen, caffeine and pyrilamine maleate capsule

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:21130-390
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg		
CAFFEINE (CAFFEINE)	CAFFEINE	60 mg		
PYRILAMINE MALEATE (PYRILAMINE)	PYRILAMINE MALEATE	15 mg		

Inactive Ingredients				
Ingredient Name	Strength			
CROSCARMELLOSE SODIUM				
HYPROMELLOSES				
MAGNESIUM STEARATE				
POLYDEXTROSE				
POLYETHYLENE GLYCOLS				
STEARIC ACID				
TITANIUM DIO XIDE				
TRIACETIN				

Product Characteristics			
Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	44;390
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21130-390-10	1 in 1 CARTON			
1		40 in 1 BOTTLE, PLASTIC			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	04/29/2002		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(21130-390)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867894	MANUFACTURE(21130-390)		

Revised: 11/2013 Safeway