

**SYNCOL MAX- acetaminophen, caffeine, pyrilamine maleate tablet, film coated**

**Laboratorios Sanfer, S.A. de C.V.**

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**Syncol 44-390**

***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
- water-weight gain
- cramps
- backache
- fatigue
- muscle aches

***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**

- 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**

- 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**

- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- use caution when driving a motor vehicle or operating machinery
- 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 rate. 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

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 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 directed**
- 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°C-30°C (59°F-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?***

**Call 1-(833)-604-1084** (English and Spanish) 8:00 AM-5:00 PM CST, Monday-Friday

### **Principal Display Panel**

**SYNCOL MAX®**

**Acetaminophen/Caffeine/Pyrilamine Maleate**  
Pain reliever/Diuretic/Antihistamine

*Relieves Menstrual Cramps*

√**Fatigue**    √**Bloating**

√**Headache**   √**Backache**

Actual Size

**12** Caplets

sanfer®

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

Manufactured for: Laboratorios Sanfer  
S.A. de C.V. Blvd. Adolfo López Mateos  
No. 314, Col. Tlacopac, CDMX, 01049. Mexico  
This product is produced in compliance  
with all United States regulatory and quality  
requirements for pharmaceutical product.  
50844 ORG062339002

<b>Drug Facts (continued)</b>	<p>■ see end flap for expiration date and lot number</p> <p>■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</p> <p>cellulose, polydextrose, polyethylene glycol, powder, silicon dioxide, stearic acid, titanium dioxide, triacetin</p>
<b>Drug Facts (continued)</b>	<p>cross polyvidone, hypromellose, magnesium stearate, microcrystalline cellulose</p> <p>8:00 AM-5:00 PM CST, Monday-Friday          Call 1-(833)-604-1084 (English and Spanish)  <b>Questions or comments?</b></p>

<b>Drug Facts (continued)</b>	<p>may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <p>■ with other drugs containing acetaminophen</p> <p>■ 3 or more alcoholic drinks every day while using this product</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <p>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p>■ if you have ever had an allergic reaction to this product or any of its ingredients</p> <p><b>Ask a doctor before use if you have</b></p> <p>■ difficulty in urination due to enlargement of the prostate gland</p> <p>■ liver disease ■ glaucoma</p> <p>■ a breathing problem such as emphysema or chronic bronchitis</p> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <p>■ taking the blood thinning drug warfarin</p> <p>■ taking sedatives or tranquilizers</p> <p><b>When using this product</b></p> <p>■ drowsiness may occur</p> <p>■ avoid alcoholic beverages</p> <p>■ alcohol, sedatives, and tranquilizers may increase drowsiness</p> <p>■ excitability may occur, especially in children</p> <p>■ use caution when driving a motor vehicle or operating machinery</p>
<b>Drug Facts (continued)</b>	<p>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 rate. The recommended dose of this product contains about as much caffeine as a cup of coffee.</p> <p><b>Stop use and ask a doctor if</b></p> <p>■ new symptoms occur ■ redness or swelling is present</p> <p>■ pain gets worse or lasts more than 10 days</p> <p>■ fever gets worse or lasts more than 3 days</p> <p>■ these could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. 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.</p> <p><b>Directions</b></p> <p>■ do not take more than directed</p> <p>■ adults and children 12 years and over: take 2 caplets with water ■ repeat every 6 hours, as needed</p> <p>■ do not exceed 6 caplets per day</p> <p>■ children under 12 years: ask a doctor</p> <p><b>Other Information</b></p> <p>■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN</p>



Manufactured for: Laboratorios Sanfer S.A. de C.V., Blvd. Adolfo López Mateos No. 314, Col. Tacopac, CDMX, 01049, Mexico

This product is produced in compliance with all United States regulatory and quality requirements for pharmaceutical product.

50844 ORG062339002

<b>Drug Facts (continued)</b>	<p>for the temporary relief of these symptoms associated with menstrual periods: ■ bloating ■ headache ■ muscle aches ■ water-weight gain ■ cramps ■ backache ■ fatigue</p> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours.</p> <p>Pyrilamine maleate 15 mg.....Antihistamine</p>
<b>Drug Facts (continued)</b>	<p><b>Active ingredients (in each caplet)</b></p> <p>Acetaminophen 500 mg.....Pain reliever</p> <p>Caffeine 60 mg.....Diuretic</p> <p>Pyrilamine maleate 15 mg.....Antihistamine</p> <p><b>Purpose</b></p> <p>Pain reliever</p> <p><b>KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION</b></p>

B-1090-390-02  
ORG062339002

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

No Print/Varnish Area  
Lot no & Expiration Date

# SYNCOL MAX<sup>®</sup>

## Acetaminophen/Caffeine/Pyrilamine Maleate

Pain reliever/Diuretic/Antihistamine

### RELIEVES Menstrual Cramps

✓ Fatigue    ✓ Bloating  
✓ Headache   ✓ Backache

Actual Size

12 Caplets    sanfer<sup>®</sup>

Syncol 44-390

**SYNCOL MAX**  
acetaminophen, caffeine, pyrilamine maleate tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83393-390
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg
<b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;390
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83393-390-02	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/09/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/09/2024	

**Labeler** - Laboratorios Sanfer, S.A. de C.V. (810007732)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(83393-390)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(83393-390) , pack(83393-390)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(83393-390)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(83393-390)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(83393-390)

Revised: 4/2024

Laboratorios Sanfer, S.A. de C.V.