

COMFORT-TIME- acetaminophen, caffeine, and pyrilamine maleate tablet, film coated
Time Cap Labs, 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.

TCL COMFORT TIME 347R

active ingredients (in each tablet)

Acetaminophen 500 mg

Caffeine 60 mg

Pyrilamine maleate 15 mg

active ingredients (in each tablet)

Acetaminophen 500 mg

Caffeine 60 mg

Pyrilamine maleate 15 mg

Uses

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

cramps

bloating

water-weight gain

headache

backache

breast tenderness

fatigue

muscle aches

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Warnings

Liver warning:

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

more than 8 tablets in 24 hours, which is the maximum daily amount

with other drugs containing acetaminophen

3 or more alcoholic drinks 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
glaucoma
a breathing problem such as emphysema or chronic bronchitis

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Ask a doctor or pharmacist before use if you are
taking the blood thinning drug warfarin
taking sedatives or tranquilizers

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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 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.

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Stop use and ask a doctor if
new symptoms occur
redness or swelling is present
pain gets worse or lasts more than 10 days

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

Keep out of reach of children.

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Other information

store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
use by expiration date on package

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, stearic acid, titanium dioxide

tcl blister 24 tablets



COMFORT-TIME

acetaminophen, caffeine, and pyrilamine maleate tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49483-347

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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SF2WJZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	TCL;347
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-347-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/30/2011	

Labeler - Time Cap Labs, Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
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