# PAIN RELIEVER- acetaminophen tablet Stephen L. LaFrance Pharmacy, 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.

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#### **Pain Reliever**

## Active ingredient

Acetaminophen 500 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - toothache
  - the common cold
  - minor pain of arthritis
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

## Warning

This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

#### 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

liver disease.

# Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

#### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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 (1-800-222-1222) right away. Quick 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 (see overdose warning)
- adults and children 12 years and over
  - take 2 caplets every 4 to 6 hours while symptoms last
  - do not take more than 8 caplets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

# **Inactive Ingredients**

caster oil, hypromellose, povidone, sodium starch glycolate\*, starch, stearic acid \*may contain this ingredient

#### Questions or comments?

1-800-426-9391

#### PRODUCT PACKAGING

#### select brand®

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EXTRA STRENGTH/NON-ASPRIN

#### PAIN RELIEVER

NDC 15127-735-08

SAFETY SEALED

PAIN RELIEVER/FEVER REDUCER

NON-ASPRIN ACETAMINOPHEN

†Compare to the active Ingredient of Extra Strength Tylenol®

# 500 mg EACH

**100** CAPLETS

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

 $\dagger$ This product is manufactured or distributed by McnNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Caplets.

50844 REV0213B17512

Distributed by:

### **SELECT BRAND® DISTRIBUTORS**

Pine Bluff, AR 71603 USA AC (870) 535-3635



Select Brand 44-175

# PAIN RELIEVER acetaminophen tablet Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:15127-735 Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSES	
POVIDONES	
STEARIC ACID	
CASTOR OIL	
SO DIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics			
Color	WHITE	Score	no score
Shape	CAPSULE (Tablet)	Size	18 mm
Flavor		Imprint Code	44;175
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-735-08	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		
2	NDC:15127-735-09	1 in 1 CARTON		
2		24 in 1 BOTTLE, PLASTIC		
3	NDC:15127-735-16	1 in 1 CARTON		
3		50 in 1 BOTTLE, PLASTIC		
4	NDC:15127-735-05	500 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/02/1993	

# **Labeler** - Stephen L. LaFrance Pharmacy, Inc. (043562370)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(15127-735)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(15127-735)

Revised: 10/2013