EXTRA STRENGHTH ACETAMINOPHEN- acetaminophen tablet OPMX LLC

Temp X Caplets

Active Ingredient (in each tablet)

Acetaminophen 500mg

Purpose

Pain reliever/fever reducer

Uses

Temporary relieves minor aches and pains due to:

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3000 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

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

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 reccomended 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 use more than directed (see overdose warning)

Adults and children 12 years of age and older:

- Take 2 caplets every 6 hours while symptoms last.
- Do not take more than 6 caplets in 24 hours, unless directed by a doctor
- Do not use more than 10 days unless directed by a doctor.

Children under 12 years of age: Do not use this extra strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

Other Information

- store at controlled room temperature 20-25°C (68-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

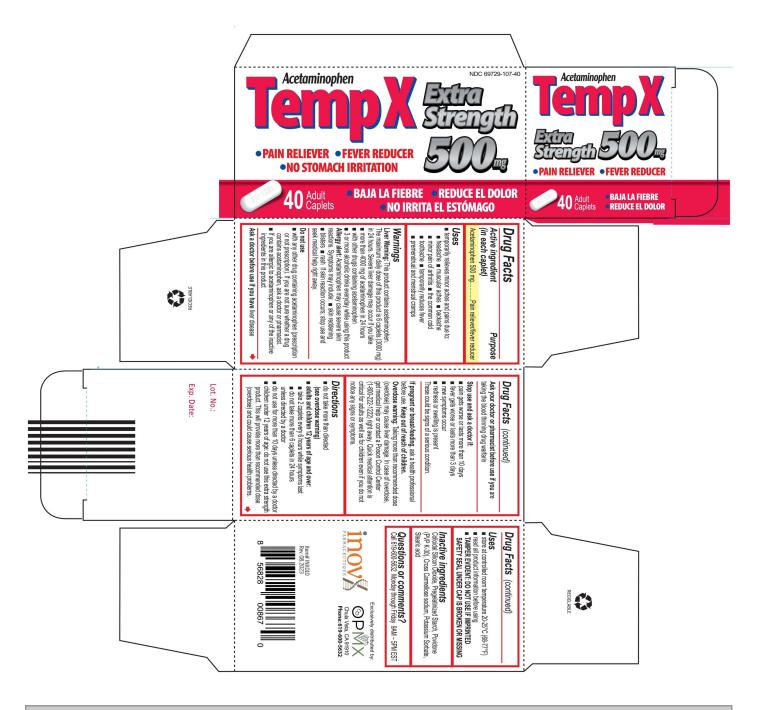
Colloidal silicon dioxide, pregelatinized starch, povidone (pvp k-30), croscarmellose sodium, potassium sorbate, stearic acid

Questions or Comments

Call 619-600-5632 Monday through Friday 9AM-5PM EST

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





EXTRA STRENGHTH ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-107
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
POVIDONE K30 (UNII: U725QWY32X)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	AP500
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69729-107- 40	1 in 1 CARTON	07/31/2017		
1		40 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/31/2017	

Labeler - OPMX LLC (029918743)

Establishment				
Name	Address	ID/FEI	Business Operations	
Health Pharma USA LLC		080804485	manufacture(69729-107)	

Revised: 12/2023 OPMX LLC