

EXTRA STRENGTH 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 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 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

NDC 69729-107-40

Acetaminophen **Temp X**

Extra Strength 500_{mg}

● PAIN RELIEVER ● FEVER REDUCER

SEE CARTON FOR COMPLETE DRUG FACTS

Drug Facts

Active ingredient (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever/fever reducer

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 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

Allergy alert: Acetaminophen may cause severe skin reactions.
Symptoms may include: ■ skin reddening ■ blisters ■ rash If skin reaction occurs; stop use and seek medical help right away.

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years of age and over:
- 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 for 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 recommended dose (overdose) and could cause serious health problems.

Do not use if imprinted safety seal under cap is broken or missing

40 Adult Caplets

- BAJA LA FIEBRE
- REDUCE EL DOLOR

FARMACEUTICAL

Exclusively distributed by:

Chula Vista, CA 91910

Lot. No.:

Exp. Date:

NDC 69729-107-40

Acetaminophen Temp X Extra Strength 500 mg

- PAIN RELIEVER • FEVER REDUCER
- NO STOMACH IRRITATION

Acetaminophen Temp X Extra Strength 500 mg

- PAIN RELIEVER • FEVER REDUCER



40 Adult Caplets

• **BAJA LA FIEBRE** • **REDUCE EL DOLOR**
• **NO IRRITA EL ESTÓMAGO**



40 Adult Caplets

• **BAJA LA FIEBRE**
• **REDUCE EL DOLOR**



Do not use

- with any other drug containing acetaminophen (prescription or not prescribed). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease.

Warnings

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 4000 mg of acetaminophen in 24 hours.

Do not take other drugs containing acetaminophen.

Alcohol, acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If skin reaction occurs, stop use and seek medical help right away!

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 500 mg Pain reliever/fever reducer

Purpose

- temporarily 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

Uses

- temporarily 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

Directions

Take 1 caplet every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours. Do not use for more than 10 days unless directed by a doctor.

Lot No.:
Exp. Date:

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years of age and over:
 - 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 for 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 recommended dose (overdose) and could cause serious health problems.

Warnings

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 4000 mg of acetaminophen in 24 hours.

Do not take other drugs containing acetaminophen.

Alcohol, acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If skin reaction occurs, stop use and seek medical help right away!

Drug Facts (continued)

Ask your 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 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.

Uses

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Directions

Take 1 caplet every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours. Do not use for more than 10 days unless directed by a doctor.



Humint INXD10
Rev. 08/2023

innov
Pharmaceuticals

Exclusively distributed by:
PNTX
Chula Vista, CA 92010
Phone: 619-490-5432

Drug Facts (continued)

Uses

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

Inactive ingredients

Chitosan Sponex, Docusone, Hydroxyethyl Starch, Polydioxanone (PDS), Croscarmellose sodium, Potassium Sulfate, Stearic acid

Questions or comments?
Call 619-500-5632. Mon-Fri 9AM - 5PM EST

Directions

Take 1 caplet every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours. Do not use for more than 10 days unless directed by a doctor.

EXTRA STRENGTH 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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

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

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: 3/2025

OPMX LLC