

TOPCARE PAIN RELIEF- acetaminophen tablet
Praxis, LLC

Topcare Health Pain Relief Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

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

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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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:In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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	<ul style="list-style-type: none">• 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	ask a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain one or more of these ingredients

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare® health

COMPARE TO EXTRA STRENGTH TYLENOL® CAPLETS ACTIVE INGREDIENT

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN 500 mg

PAIN RELIEVER • FEVER REDUCER

500 CAPLETS

For Adults

actual size

TopCare® health

NDC 36800-484-90

COMPARE TO EXTRA STRENGTH TYLENOL® CAPLETS ACTIVE INGREDIENT

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN 500 mg
PAIN RELIEVER • FEVER REDUCER

500 CAPLETS For Adults actual size

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 500 mg

Purpose
Pain reliever/fever reducer

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

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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
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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 new symptoms occur
fever gets worse or lasts more than 3 days 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Questions or comments? 1-888-423-0138

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or call 1-888-423-0138

EXP LOT : 48490 88 F10

TOPCARE PAIN RELIEF

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-210
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L484
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-210-01	2 in 1 PACKAGE	07/15/1987	
1		500 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-210-02	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/15/1987	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/15/1987	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-210) , pack(59368-210) , label(59368-210)

Revised: 1/2023

Praxis, LLC