

PUREGEN LABS ACETAMINOPHEN- acetaminophen liquid
Advanced Rx LLC

Puregen APAP 001

Acetaminophen 500 mg

Pain Reliever/Fever Reducer

USES

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

Warnings

Liver Warning: This product contains acetaminophen. The maximum daily dose of this product is 90 mL in 24 hours. Severe liver damage may occur if you take

- more than 120 mL (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 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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have liver disease.

Ask a doctor before use if you are taking the blood thinning drug warfarin

When using this product: Do not exceed recommended dose.

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. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than directed

Age	Dose
Adults and children 12 years of age and older	Take 1 to 2 tablespoonfuls every 4 to 6 hours as needed. Not more than 6 tablespoonfuls in 24 hours
Children under 12 years	do not use

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Questions or comments? 1-800-630-8895

Drug Facts	
Active ingredient (in each 15 mL Tablespoonful)	Purposes
Acetaminophen 500 mg.....	Pain Reliever / Fever Reducer
Uses	• temporarily relieves minor aches and pains • temporarily reduces fever
Warnings	Liver Warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablespoonfuls in 24 hours. Severe liver damage may occur if you take • more than 8 tablespoonfuls (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 are allergic to acetaminophen or any of the inactive ingredients in this product
Ask a doctor before use if you have	liver disease.
Ask a doctor before use if you are taking the blood thinning drug warfarin.	
When using this product: Do not exceed recommended dose.	
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.



Compare to the active ingredient
in Tylenol® Extra Strength®

Adult Extra Strength ACETAMINOPHEN 500 mg per 15 ml

- Pain Reliever
- Fever Reducer
- Alcohol Free

RAPID BURST LIQUID

For ages 12 years and over

8 fl oz (237 ml)



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions • do not take more than directed

Age	Dose
Adults and children 12 years of age and older	Take 1 to 2 Tablespoonfuls every 4 to 6 hours as needed; not more than 6 Tablespoonfuls in 24 hours
Children under 12 years	Do not use

Other information

- store at room temperature 20°- 25°C (68°-77°F)
- protect from freezing • protect from light
- **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn, broken or missing.

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Questions or comments? call toll-free 1-800-630-8895

Manufactured for: ADVANCED RX LLC
1928 NE 163rd St, North Miami Beach, FL 33162 U.S.A

*This product is not manufactured or distributed by the owner of the registered trademark Tylenol®.

Code #: L-230
Rev. 04/24

Lot #:
Exp. Date:



PUREGEN LABS ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CITRIC ACID (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-001-13	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/01/2025	

Labeler - Advanced Rx LLC (042795108)

Revised: 12/2025

Advanced Rx LLC