

**PUREGEN LABS ACETAMINOPHEN- acetaminophen liquid**  
**Advanced Rx LLC**

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**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 drug 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 get 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)  
Acetaminophen 500 mg.....Pain Reliever / Fever Reducer  
**Purposes**  
**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)**

  
  
**CHERRY FLAVOR**

**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  
1942 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:  
  
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## PUREGEN LABS ACETAMINOPHEN

acetaminophen liquid

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg in 15 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)				
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)				
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)				
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)				
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)				
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)				
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:80513-001-13	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2025	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug		M013	12/01/2025	

**Labeler** - Advanced Rx LLC (042795108)

Revised: 12/2025

Advanced Rx LLC