

ED APAP- acetaminophen liquid
EDWARDS PHARMACEUTICALS, INC.

Ed-EdAPAPChild 0057

Drug Facts

Active ingredient (in each 5mL = 1 teaspoon)

Acetaminophen 160 mg

Purpose

Pain Reliever / Fever Reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headaches
 - sore throat
 - immunizations
 - toothache

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen.

Sore throat warning

if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

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

Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

When using this product

- **do not exceed recommended dose (see overdose warning)**

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days. These could be signs of a serious condition.

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 right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **This product does not contain directions or complete warnings for adult use**
- shake well before using
- find right dose on chart below. If possible, use weight to dose: otherwise, use age.
- if needed, repeat dose every 4 hours
- do not use more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor.

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
under 24	under 2	Ask a doctor
24-35	2-3	1 tsp or 5 mL
36-47	4-5	1 1/2 tsp or 7.5 mL
48-59	6-8	2 tsp or 10 mL
60-71	9-10	2 1/2 tsp or 12.5 mL
72-95	11	3 tsp or 15 mL

Other information

- Store at room temperature 15°-30° C (59°-86° F)
- Protect from freezing
- Protect from Light.
- **Each teaspoon (5mL) contains:**sodium 7 mg

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS 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? COMMENTS?

Call 1-800-543-9560

PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label**E****NDC 00485-0057-08****ED-APAP
CHILDREN'S****ACETAMINOPHEN
ORAL SOLUTION,
ALCOHOL FREE
CHERRY FLAVORED**

Contains 160 mg
Acetaminophen in each
teaspoon (5mL)

8 fl oz (236 ml)***Manufactured for:******EDWARDS
PHARMACEUTICALS, INC.
111 Mulberry Street
RIPLEY, MS 38663***



NDC 00485-0057-08

ED-APAP CHILDREN'S

ACETAMINOPHEN
ORAL SOLUTION,
ALCOHOL FREE
CHERRY FLAVORED

Contains 160 mg
Acetaminophen in each
teaspoon (5 mL)

Manufactured by:
EDWARDS
Pharmaceuticals, Inc.
Berwyn, PA 19312

8 oz (237mL)

ED-APAP

Drug Facts

Active ingredient (in each 5 mL teaspoonful) **Purpose**
Acetaminophen 160 mg Pain Reliever/Fever Reducer

Uses temporarily reduces fever ■ relieves minor aches and pains due to ■ the common cold ■ flu ■ headaches ■ sore throat ■ immunizations ■ toothache

Warnings **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes ■ more than 5 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen. **Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. **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 your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

When using this product ■ do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if ■ new symptoms occur ■ redness or swelling is present ■ pain gets worse or lasts for more than 5 days ■ fever gets worse or lasts for more than 3 days. These could be signs of a serious condition.

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 right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions ■ This product does not contain directions or complete warnings for adult use ■ use dosing cup provided ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose: otherwise, use age ■ if needed, repeat dose every 4 hours ■ do not use more than 5 times in 24 hours ■ do not give for more than 5 days unless directed by a doctor.

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
under 24	under 2	Ask a doctor
24-35	2-3	1 tsp or 5 mL
36-47	4-5	1 1/2 tsp or 7.5 mL
48-59	6-8	2 tsp or 10 mL
60-71	9-10	2 1/2 tsp or 12.5 mL
72-95	11	3 tsp or 15 mL
over 95	12 to adult	4 tsp or 20 mL

Other information: ■ Store at room temperature 59°-86°F (15°-30°C) ■ Protect from freezing ■ Protect from light.
TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS 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? 1-800-543-9560

L-214

Rev.: 04/23

Lot#
Exp. Date:



ED APAP

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0485-0057
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

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

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0057-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/07/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/07/2012	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 12/2025

EDWARDS PHARMACEUTICALS, INC.