ED APAP- acetaminophen liquid
EDWARDS PHARMACEUTICALS, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ED APAP

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

citric acid, FD&C red #40, flavor, glycerin, PEG 400, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

QUESTIONS? COMMENTS?

Call 1-800-543-9560

PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label

E

NDC 00485-0057-08

ED-APAP
CHILDREN'S

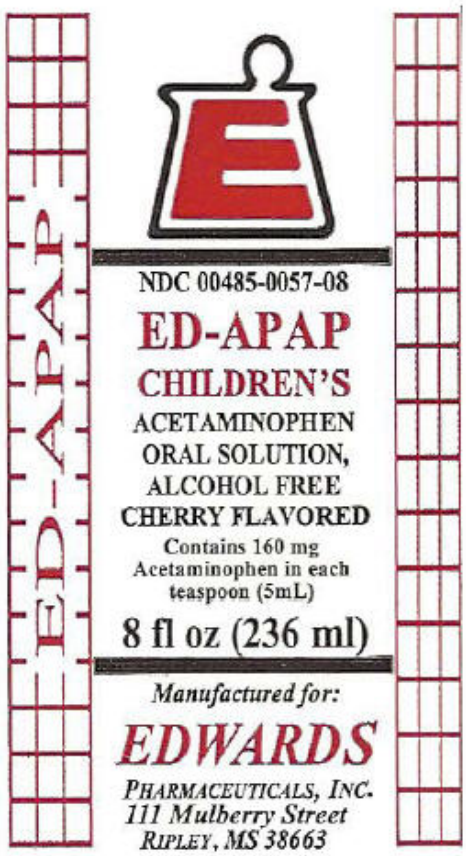
ACETAMINOPHEN
ORAL SOLUTION,
ALCOHOL FREE
CHERRY FLAVORED

Contains 160 mg
Acetaminophen in each
teaspoon (5mL)

8 fl oz (236 ml)

Manufactured for:

EDWARDS
PHARMACEUTICALS, INC.
111 Mulberry Street
RIPLEY, MS 38663



Drug Facts

Active Ingredient (in each 5mL = 1 teaspoon) — **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.

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.

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QUESTIONS? COMMENTS?
Call 1-800-543-9560

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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**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

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 not final	part343	03/07/2012	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 8/2023 EDWARDS PHARMACEUTICALS, INC.