

ACETAMINOPHEN- acetaminophen liquid
Safecor Health, LLC

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.

Acetaminophen Oral Liquid
Unit Dose Oral ENFit® Syringe
(160 mg / 5 mL)

Active Ingredient (per 5 mL = 1 teaspoonful)

Acetaminophen 160 mg

Purpose

Pain Reliever / Fever Reducer

Uses:

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

Warnings:

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:

- more than 5 doses is taken in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday 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.

Ask a doctor before use if you have

a 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 in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 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
- Find dose in chart below
- If possible, use weight to dose, otherwise use age
- Dosage may be repeated every 4 hours, or as directed by a doctor
- Do not give more than 5 doses in 24 hours

Weight (lbs)	Under 24	24-35	36-47	48-59	60-71	72-95	over 95
Age (years)	Under 2	2 to 3	4 to 5	6 to 8	9 to 10	11	12 to adult
Dosage mL (tsp)	Consult Physician	5 mL (1 tsp)	7.5 mL (1 1/2 tsp)	10 mL (2 tsp)	12.5 mL (2 1/2 tsp)	15 mL (3 tsp)	20 mL (4 tsp)

Other Information:

- Store at room temperature 15°C- 30°C (59°F-86°F)
- Protect from freezing
- Protect from light
- Aspirin Free
- Alcohol Free
- **TAMPER-EVIDENT:** Do not use if foil seal over syringe blister is torn, broken, or missing or if endcap is broken, missing, or separated from syringe.
- For more info call 1-800-447-1006

Inactive Ingredients:

Artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose.

NDC: 48433-401-05 Acetaminophen Oral Liquid Unit Dose Oral ENFit® Syringe (160 mg / 5 mL)

NDC: 48433-401-25 Box of 25 Unit-Dose Oral ENFit® Syringes, each unit-dose syringe delivers 5 mL

For Oral Use Only.

For Institutional Use Only.

This Package Is Not Child Resistant.

Mfd. in the U.S.A.

Distributed by: Safecor Health, LLC

4060 Business Park Drive, Columbus, OH 43204

07/2022 PN5727

Rev:

Principal Display Panel

SAFECOR HEALTH

NDC 48433-401-05

Acetaminophen Oral Liquid

160 mg / 5 mL

(Delivers 5 mL)

SAFECOR
HEALTH

NDC: 48433-401-05

Cherry Flavor

- Alcohol Free •Aspirin Free
- Store at room temperature
15°C-30°C (59°F-86°F)
- Protect from Light •Protect from Freezing
- For Oral Use Only •For Institutional Use Only

Distributed by: Safecor Health, LLC,
Columbus, Ohio 43204

07/2022 PN5913

SAFECOR
HEALTH

NDC: 48433-401-05

Acetaminophen Oral Liquid

160 mg / 5 mL

(Delivers 5 mL)



4843340105

ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-401(NDC:54859-809)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-401-25	25 in 1 BOX	11/01/2022	
1	NDC:48433-401-05	5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/01/2022	

Labeler - Safecor Health, LLC (828269675)**Establishment**

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	repack(48433-401) , relabel(48433-401)