

**LIQUID ACETAMINOPHEN- acetaminophen liquid
KRAMER NOVIS**

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.

Liquid Acetaminophen

Drug Facts

Active ingredient (in each 5 mL tsp)

Acetaminophen, 160 mg

Purpose

Pain reliever/Fever reducer

Uses:

Temporarily relieves of minor aches and pains due to • headache • backache • muscular aches • 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:

- adults take more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen (prescription or nonprescription)
- adults has 3 or more alcoholic drinks 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 product containing acetaminophen (prescription or nonprescription), this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

WHEN USING THIS PRODUCT, DO NOT EXCEED RECOMMENDED DOSE

Ask a doctor before use if you have a liver disease.

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

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 (1-800-222-1222) right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions

Dosage may be repeated every 4 hours, or as directed by doctor.

Do not exceed recommended dose.

Find dose in chart below. If possible, use weight to dose, otherwise use age.

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 teaspoonful (tsp)	consult a doctor	1 tsp (5 mL)	1 1/2 tsp (7.5 mL)	2 tsp (10 mL)	2 1/2 tsp (12.5 mL)	3 tsp (15 mL)	4 tsp (20 mL)

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F). Do not refrigerate.
- Protect from light. Avoid excessive heat or humidity.

Inactive ingredients

Cherry flavor, citric acid, FD&C Red #40, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sorbitol, sucralose

Questions or comments?

Call weekdays from 8 AM to 4 PM AST at **787-767-2072**.

Manufactured in the USA for Kramer Novis, San Juan, PR 00917

Compare to the active ingredient of Tylenol® Liquid*

✓ **Alcohol Free**

✓ **Aspirin Free**

Cherry Flavor

***This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Liquid.**

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER CAP IS TORN, BROKEN OR MISSING.

www.kramernovis.com

Packaging

Drug Facts

Active Ingredient (in each 5 mL tsp) **Purpose**
 Acetaminophen, 160 mg Pain reliever/Fever reducer

Uses: Temporarily relieves minor aches and pains due to: ■ headache
 ■ backache ■ muscular aches ■ 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:
 ■ adults take more than 6 doses in 24 hours, which is the maximum daily amount
 ■ child takes more than 5 doses in 24 hours, which is the maximum daily amount
 ■ taken with other drugs containing acetaminophen (prescription or nonprescription)
 ■ adult has 3 or more alcoholic drinks 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 product containing acetaminophen (prescription or nonprescription), this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

WHEN USING THIS PRODUCT, DO NOT EXCEED RECOMMENDED DOSE

Ask a doctor before use if you have a liver disease.

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

Stop use and ask 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.

NDC 52083-663-16

Liquid Acetaminophen

Pain Reliever / Fever Reducer

Compare to the active ingredient of Tylenol® Liquid*

Acetaminophen, 160 mg per 5 mL

- ✓ Alcohol Free
- ✓ Aspirin Free



Cherry Flavor

Net Content: 16 fl oz (473 mL)

**Drug Facts (continued)**

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. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions:

- Dosage may be repeated every 4 hours, or as directed by doctor
- **Do not exceed recommended dose.**
- Find dose in chart below ■ If possible, use weight to dose, otherwise use age

Weight (lbs)	Under 24	24-35	36-47	48-59	60-71	72-85	Over 85
Age (years)	Under 2	2 to 3	4 to 5	6 to 8	9 to 10	11	12 to adult
Dosage Teaspoonful (tsp)	consult a doctor	1 tsp (5 mL)	1 ½ tsp (7.5 mL)	2 tsp (10 mL)	2 ½ tsp (12.5 mL)	3 tsp (15 mL)	4 tsp (20 mL)

Other information

- Store at controlled room temperature 15° - 30°C (59° - 86°F). Do not refrigerate.
- Protect from light. Avoid excessive heat or humidity.

Inactive ingredients

Cherry flavor, citric acid, FD&C Red #40, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sorbitol, sucralose

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Rev. 01/20

Lot No.
Exp. Date

UNVARNISH AREA

LIQUID ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-663
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
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Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-663-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/02/2020	

Labeler - KRAMER NOVIS (090158395)

Revised: 3/2020

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