

ACETAMINOPHEN- acetaminophen liquid

Proficient Rx LP

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

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Acetaminophen, USP 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- arthritis
- the common cold
- toothache
- menstrual cramps
- reduces fever

Warnings

Liver Warning

This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 8 teaspoonfuls (40 mL) in 24 hours, which is the maximum daily amount
- 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.

Ask a doctor before use

if you have health issues especially liver disease.

Ask a doctor or pharmacist before use

if you are taking other drugs, including the blood thinner warfarin.

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.

- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Stop use and ask a doctor if

- new symptoms occur such as rash, hives, itching or hoarseness
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- symptoms do not improve

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. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

Do not exceed recommended dosage.

Overdose Warnings

Taking more than the recommended dose (overdose) can cause serious health problems, including liver damage.

- **adults and children 12 years of age and older:** take 2 teaspoonfuls (10 mL) every 6 hours; do not exceed 8 teaspoonfuls (40 mL) in 24 hours
- **children under 12 years of age:** Under the direct guidance of a licensed professional, doctor, or pharmacist.

Other information

If dispensed, dispense in a tight, light resistant container with a child-resistant cap.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)

Inactive ingredients

Bitter Mask, Cherry Flavor, Citric Acid, FD&C Red No. 40, Glycerin, Polyethylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate Dihydrate, Sodium Saccharin, Sorbitol.

Questions?

You may report side effects by calling Westminster M-F (9 a.m. to 5 p.m. EST), at 1-844-7294 or FDA at 1-800-FDA-1088.

PRINCIPAL DISPLAY PANEL - 4 fl. oz. (118 mL) Bottle Label

NDC 71205-730-04

Acetaminophen
Liquid
160 mg/5 mL

Pain Reliever / Fever Reducer
Sugar Free / Alcohol Free
Aspirin Free

CHERRY FLAVOR

4 fl. oz. (118 mL)



Scan Here



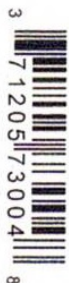
NDC 71205-730-04

Relabeled By Proficient Rx LP
Thousand Oaks, CA 91320

Acetaminophen Liquid 160mg/ 5mL
4 fl. oz. (118 mL) Oral Solution
Lot #:00000 SN# MASTER
NDC 71205-730-04 Exp:00/00/00

Acetaminophen Liquid 160mg/ 5mL
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Acetaminophen Liquid 160mg/ 5mL
4 fl. oz. (118 mL) Oral Solution
Lot #:00000 SN# MASTER
NDC 71205-730-04 Exp:00/00/00



Acetaminophen Liquid 160mg/ 5mL

4 fl. oz. (118 mL) Oral Solution

Each 5 mL teaspoonful contains: Acetaminophen, USP
160 mg Pain Reliever/fever reducer

See Bottle. Red cherry flavor, Sugar Free / Alcohol Free / Aspirin Free

Product ID: SA073004

Mfr. For: Westminster Pharmaceuticals, LLC Nashville, TN 37217

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children



GTIN: 00371205730048
SN# MASTER
Exp. 00/00/00
Lot #:00000

ACETAMINOPHEN

acetaminophen liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-730(NDC:69367-323) |
| 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) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SORBITOL (UNII: 506T60A25R) | |

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:71205-730-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/12/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 05/05/2021 | |

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|---------------------|
| Proficient Rx LP | | 079196022 | RELABEL(71205-730) |

Revised: 12/2022

Proficient Rx LP