LIL DRUG STORE CHILDRENS PAIN AND FEVER- acetaminophen suspension Lil' Drug Store Products, 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.

Children's Pain & Fever, Lil' Drug Store ® Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- temporarily relieves minor aches and pains due to
 - the common cold
 - flu
 - headache
 - sore throat
 - 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

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.

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 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 more than 5 days
- fever gets worse or lasts 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 (1-800-222-1222) 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
- do not take more than directed (see Overdose warning)
- shake well before using
- mL = milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	Dose (mL) *
-------------	------------	-------------

under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

^{*} or as directed by a doctor

Other information

- each 5 mL contains: sodium 2 mg
- store between 20-25°C (68-77°F)
- do not refrigerate
- see bottom panel for lot number and expiration date

Inactive ingredients

acesulfame potassium, butylparaben, carboxymethylcellulose sodium, citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

Call toll free 1-877-507-6516 (M-F 8AM-4:30PM CST)

Product distributed by:

Lil' Drug Store Products, Inc. 1201 Continental Place NE Cedar Rapids, IA 52402

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

QUALITY
* GUARANTEED *

Compare to the Active Ingredient in Children's Tylenol®
Oral Suspension**

Children's Pain & Fever

Acetaminophen 160 mg per 5 mL Pain Reliever/Fever Reducer

Oral Suspension For ages 2-11 years

Cherry

4 FL OZ (118 mL)

Lil' Drug Store [®]

Children's Pain & Fever

Acetaminophen

160 mg per 5 mL Pain Reliever/Fever Reducer





Compare to the Active Ingredient in Children's Tylenol® Oral Suspension**

Children's Pain & Fever

Acetaminophen

160 mg per 5 mL

Pain Reliever/Fever Reducer

Oral Suspension For ages 2-11 years

Cherry

OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

TAMPER EVIDENT: DO NOT USE IF CARTON IS

Drug Facts

Active ingredient (in each 5 mL)

Purpose

Acetaminophen 160 mg......

..Pain reliever/fever reducer

Uses temporarily reduces fever

- temporarily relieves minor aches and pains due to
- the common cold flu
- headache
- sore throat
- **■** 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
- with other drugs containing acetaminophen

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

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.

- 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 more than 5 days
- fever gets worse or lasts 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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

PLD-D231D FC004017 68564C-US-07-16-1



Lot No.:

Exp. Date:

Drug Facts (continued)

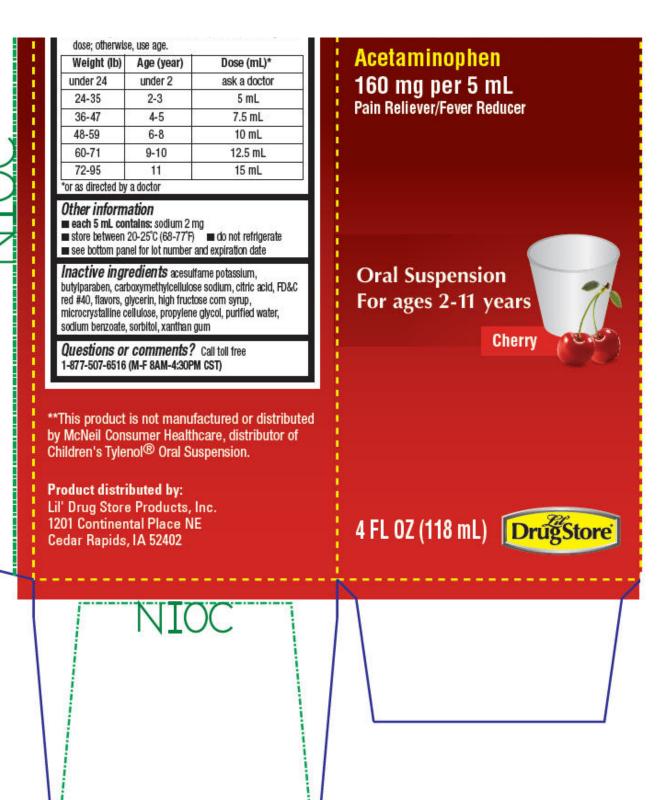
Directions

- this product does not contain directions or complete warnings for adult use
- do not take more than directed (see Overdose warning)
- shake well before using
- mL = milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- find the right dose on chart below. If possible, use weight to



Compare to the Active Ingredient in Children's Tylenol® Oral Suspension**

Children's ain & Fever



LIL DRUG STORE CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6956
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg in 5 mL		

Inactive Ingredients					
Ingredient Name	Strength				
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)					
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)					
BUTYLPARABEN (UNII: 3QPI1U3FV8)					
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)					
FD&C RED NO. 40 (UNII: WZB9127XOA)					
GLYCERIN (UNII: PDC6A3C0OX)					
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)					
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
WATER (UNII: 059QF0KO0R)					
SODIUM BENZOATE (UNII: OJ245FE5EU)					
SORBITOL (UNII: 506T60A25R)					
XANTHAN GUM (UNII: TTV12P4NEE)					

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

Packaging					
# Item Co	ode	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:6671 6956-4	5- 1 in 1 C	ARTON	12/01/2017		
1		in 1 BOTTLE, PLASTIC; Type 0: Not a ation Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part343	12/01/2014			

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 12/2022 Lil' Drug Store Products, Inc.