

PAIN AND FEVER- acetaminophen suspension
Accudial Pharmaceutical, 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
ACCUDIAL
Pain & Fever

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- the common cold
- flu
- headache
- sore throat
- toothache

temporarily reduces fever

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 nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if the child has liver disease.

Ask a doctor or pharmacist before use if the child is 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 5 days.
- 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.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Quick medical attention is critical, even if you do not notice any signs or symptoms.

Directions

- shake well before using
- if needed, repeat dose every 4 hours
- do not use more than 5 times in 24 hours
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart below to dose by age
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product. Do not use any other dosing device

Age (yr)	Dose (mL or tsp)
under 2 years	ask a doctor
2-3 years	5 mL or 1 tsp.
4-5 years	7.5 mL or 1½ tsp.
6-8 years	10 mL or 2 tsp.
9-10 years	12.5 mL or 2½ tsp.
11 years	15 mL or 3 tsp.

Other information

- **each teaspoon contains: sodium 2 mg**

Storage & Package Safety

- do not use if inner foil seal is broken or missing
- store between 20°-25°C (68°-77°F)
- see bottom panel for lot number and expiration date

Inactive ingredients

artificial flavor, citric acid, corn syrup, FD&C red #40, glycerin, microcrystalline cellulose and carboxymethyl cellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 120 mL Carton

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

ACCURATE DOSING BY WEIGHT

CONTAINS

Acetaminophen

Oral Suspension

Pain Reliever,

Fever Reducer

For Ages 2 to under 12

Alcohol Free • Aspirin Free • Ibuprofen Free

80 mg per 1/2 teaspoon

(160 mg per 5 mL)

**CHERRY
FLAVOR**

Compares to

Children's

Tylenol[®].

4 FL.OZ.

(120 mL)

NDC 45014-131-04



PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-131
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)		Acetaminophen	160 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Cherry (UNII: BUC5I9595W)				
Citric Acid Monohydrate (UNII: 2968PHW8QP)				
Corn Syrup (UNII: 9G5L16BK6N)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Glycerin (UNII: PDC6A3C0OX)				
Cellulose, Microcrystalline (UNII: OP1R32D61U)				
CarboxymethylCellulose Sodium (UNII: K679OBS311)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Water (UNII: 059QF0KO0R)				
Sodium benzoate (UNII: OJ245FE5EU)				
Sucralose (UNII: 96K6UQ3ZD4)				
Sorbitol (UNII: 506T60A25R)				
Xanthan Gum (UNII: TTV12P4NEE)				
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:45014-131-04	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part343	01/04/2010		

Labeler - Accudial Pharmaceutical, Inc. (831999201)

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Accudial Pharmaceutical, Inc.