

**CHILDRENS ACCUDIAL PAIN RELIEVER/ FEVER REDUCER- 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 reliver/Fever reducer**

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

- 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 before use if your child is under 6 mos. or 12 lbs. OR over 12 yrs. or 95 lbs.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

When using this product: Do not use more than directed.

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). Prompt 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.

- **shake well before using**
- if needed, repeat dose every 4 hours
- do not use more than 5 times in 24 hours
- *when weight is known:* use the rotating bottle label to find the child's weight and read the correct dose. This is the most accurate dose.
when weight is unknown: use the age chart on the rotating label.
- use only enclosed dosing syringe and adapter to dose this product. Do not use any other dosing device

Age (yr)	Dose (mL or tsp)
under 6 mos.	ask a doctor
6 mos. to under 2	2.5 mL or ½ tsp.
2 to under 4	5 mL or 1 tsp.
4 to under 6	7.5 mL or 1½ tsp.
6 to under 9	10 mL or 2 tsp.
9 to under 11	12.5 mL or 2½ tsp.
11 to under 12	15 mL or 3 tsp.
or as directed by a doctor	

tsp. = teaspoon

mL = milliliter

Ask a doctor before use if your child is under 6 mos. or 12 lbs. OR over 12 yrs. or 95 lbs.

Other information

- **each teaspoon contains: sodium 2 mg**
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

Inactive ingredients

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

Questions?

877-434-2036

DISTRIBUTED BY ACCUDIAL PHARMACEUTICAL, INC.
Palm Beach Gardens, FL 33408

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

Children's
ACCUDIAL®

Acetaminophen
Oral Suspension

Pain Reliever / Fever Reducer

For ages 6 mos. to
under 12 yrs. or 12-95 lbs.

Alcohol Free • Aspirin Free • Ibuprofen Free

Compares to the active
ingredient in Children's
Tylenol® Oral Suspension.

ROTATING
LABEL FOR
WEIGHT-BASED
DOSING

Strawberry
Flavor

4 FL. OZ. (120 mL)
80 mg per 1/2 teaspoon
(160 mg per 5 mL)

NDC 45014-138-04

U.S. Patent Nos. 6,276,533 and 7,172,668.
Do not use if carton is opened, or if foil seal is broken or missing.
See bottom of carton for expiration date.

 ROTATING LABEL FOR WEIGHT-BASED DOSING

Children's ACCUDIAL®

DOSING SYRINGE AND
BOTTLE ADAPTER ENCLOSED.

strawberry
Flavor



Children's ACCUDIAL®

Acetaminophen Oral Suspension

Pain Reliever / Fever Reducer

*For ages 6 mos. to
under 12 yrs. or 12-95 lbs.*

Alcohol Free • Aspirin Free • Ibuprofen Free

*Compares to the active
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Tylenol® Oral Suspension.*



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IMPORTANT INSTRUCTIONS

Weight-based dosing is the most accurate way to give medications to your child.

This product has a simple rotating label that allows you to find your child's weight-based dose.



- 1,2
1) Remove foil seal.
2) Insert bottle adapter.



- 3,4
3) Hold bottle.
4) Twist label to
child's weight.



- 5,6
5) Read dose.
6) Insert syringe.



- 7,8
7) Turn bottle
upside down.
8) Fill syringe to dose.

Drug Facts

Active ingredient **Purpose**
(in each 5 mL = 1 teaspoon)
Acetaminophen 160 mgPain reliever/fever reducer

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Temporarily reduces fever

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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 before use if your child is under 6 mos. or 12 lbs. OR over 12 yrs. or 95 lbs.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

When using this product: Do not use more than directed.

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• 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.

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Drug Facts (continued)

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Inactive ingredients

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Single Oral Dose

Lbs	mL
12	2.5
14	3
16	3
18	3.5
20	4
22	4.5
24	5
26	5.5
28	5.5
30	6
32	6.5
34	7
36	7.5
38	8
40	8.5
42	8.5
44	9
46	9.5
48	10
50	10
52	11
54	11
56	11.5
58	12
60	12.5
62	13
64	13.5
66	14
68	14
70	14.5
72	15
74	15
76	15
78	15
80	15
82	15
84	15
86	15
88	15
90	15

Directions

This product does not contain directions or complete warnings for adult use.

- shake well before using



xanthan gum.

92 15

94 15

95 15

Questions? 877-434-2036

6158-0411 220



LOT

EXP.

CHILDRENS ACCUDIAL PAIN RELIEVER/ FEVER REDUCER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-138
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
Strawberry (UNII: 4J2TY8Y81V)	
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	STRAWBERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-138-04	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part343	04/25/2012		

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 4/2012

Accudial Pharmaceutical, Inc.