

**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.*

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**Children's ACCUDIAL®**  
**Pain reliever/ 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

<b>Age (yr)</b>	<b>Dose (mL or tsp)</b>
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, D&C red #33, 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**

**Bubblegum**  
*Flavor*

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

NDC 45014-137-04

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.

**Bubblegum**  
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  
ingredient in Children's  
Tylenol® Oral Suspension.*



**ROTATING  
LABEL FOR  
WEIGHT-BASED  
DOSING**

**Bubblegum**  
Flavor

4 FL OZ (120 mL)

## 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) Remove foil seal.
- 2) Insert bottle adapter.



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



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



- 7) Turn bottle upside down.
- 8) Draw dose.

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

NDC 45014-137-04

8) Fill syringe to dose.

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

**Drug Facts**

**Active ingredient** **Purpose**  
**(in each 5 mL = 1 teaspoon)**  
 Acetaminophen 160 mg .....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**  
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Ask a doctor before use if your child has liver disease.  
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 • Redness or swelling is present.  
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**Drug Facts** (continued)

- if needed, repeat dose every 4 hours
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tsp. = teaspoon                      mL = milliliter

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**Other information**

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**Inactive ingredients**

artificial flavor, citric acid anhydrous,

**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

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**Directions**

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 • shake well before using →

corn syrup, D&C red #33, FD&C red #40, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

82	15
84	15
86	15
88	15
90	15
92	15
94	15
95	15

**Questions? 877-434-2036**



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**CHILDRENS ACCUDIAL PAIN RELIEVER/ FEVER REDUCER**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45014-137
<b>Route of Administration</b>	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)	
Corn Syrup (UNII: 9G5L16BK6N)	
FD&C red no. 40 (UNII: WZB9127XOA)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
Glycerin (UNII: PDC6A3C0OX)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	

<b>Carboxymethylcellulose Sodium</b> (UNII: K679OBS311)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-137-04	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: 5/2012

Accudial Pharmaceutical, Inc.