

ACETAMINOPHEN- acetaminophen liquid
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®
Acetaminophen
Oral Solution

Drug Facts

Active ingredient Purpose (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 USP, D&C Red #33, FD&C Red #40, glycerin USP, non-crystalline sorbitol 70% USP, polyethylene glycol NF, propylene glycol, purified water, sodium benzoate, sodium saccharin.

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 Solution

Pain Reliever / Fever Reducer

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

Alcohol Free • Aspirin Free • Ibuprofen Free

Compares to the active
ingredient in Children's
Tylenol[®] *Oral Solution.*

**ROTATING
LABEL FOR
WEIGHT-BASED
DOSING**

Cherry Flavor

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

NDC 45014-130-04

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.

cherry Flavor



Children's ACCUDIAL®

Acetaminophen Oral Solution

Pain Reliever / Fever Reducer

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

Alcohol Free • Aspirin Free • Ibuprofen Free

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



**ROTATING
LABEL FOR
WEIGHT-BASED
DOSING**

cherry 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) Fill syringe to dose.

80 mg per 1/2 teaspoon
(160 mg per 5 mL)

NDC 45014-130-04

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

0.7 mL syringe to dose.

Drug Facts

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

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• the common cold • flu • headache • sore throat • toothache
Temporarily reduces fever

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• 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

Drug Facts (continued)

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| 11 to under 12 | 15 mL or 3 tsp. |
| or as directed by a doctor | |

tsp. = teaspoon mL = milliliter

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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
USP, D&C Red #33, FD&C Red #40,

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 |

Caution: 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



glycerin USP, non-crystalline sorbitol 70% USP, polyethylene glycol NF, propylene glycol, purified water, sodium benzoate, sodium saccharin.

| | |
|----|----|
| 84 | 15 |
| 86 | 15 |
| 88 | 15 |
| 90 | 15 |
| 92 | 15 |
| 94 | 15 |
| 95 | 15 |

Questions? 877-434-2036



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LOT

EXP.

6171-0811 246

ACETAMINOPHEN

acetaminophen liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:45014-130 |
| 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 |
|--|----------|
| Glycerin (UNII: PDC6A3C0OX) | |
| Sorbitol (UNII: 506T60A25R) | |
| Sodium Benzoate (UNII: OJ245FE5EU) | |
| Anhydrous citric acid (UNII: XF417D3PSL) | |
| FD&C Red no. 40 (UNII: WZB9127XOA) | |
| Water (UNII: 059QF0KO0R) | |
| saccharin sodium (UNII: SB8ZUX40TY) | |
| Propylene glycol (UNII: 6DC9Q167V3) | |

| | |
|--|--|
| Prunus Serotina Bark (UNII: 5D48E975HA) | |
| POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

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:45014-130-04 | 120 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part343 | 10/01/2011 | |

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 10/2011

Accudial Pharmaceutical, Inc.