

HARRIS TEETER INFANTS PAIN AND FEVER- acetaminophen suspension

Harris Teeter, LLC

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.

Harris Teeter, LLC Infants' Pain & Fever Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- 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 has ever had an allergic reaction to this product or any of its ingredients

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

- 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: In 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

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see overdose warning)
- shake well before using
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening.
- flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.
- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

| Weight (lb) | Age (yr) | Dose (mL)* |
|-------------|---------------|--------------|
| under 24 | under 2 years | ask a doctor |
| 24-35 | 2-3 years | 5 mL |

* or as directed by a doctor

Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

Other information

- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Infants' Tylenol® Oral Suspension

Infants' Pain & Fever

PAIN RELIEVER/FEVER REDUCER

Acetaminophen 160 mg per 5 ml

Oral Suspension

For Ages 2 to 3 Years

Alcohol Free

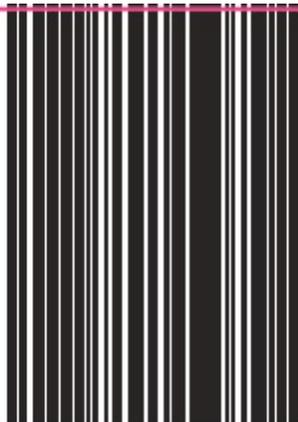
Use Only With Enclosed Syringe.

See side panel for more information

Cherry Flavor

See New Warnings

2 FL OZ (59 mL)



Compare to the active ingredient in Infants' Tylenol® Oral Suspension**



Harris Teeter™

Infants' Pain & Fever

PAIN RELIEVER/
FEVER REDUCER

Acetaminophen
160 mg per 5 mL

Oral Suspension

- For Ages 2 to 3 Years
- Alcohol Free
- Use Only With Enclosed Syringe.
See side panel for more information

**Cherry
Flavor**



See New Warnings

2 FL OZ (59 mL)

IMPORTANT:

Please see dosing chart or ask a doctor for your child's correct dose.

STEP 1. See *Directions* for the correct dose for your child.

STEP 2. Shake well before using.

STEP 3. Push air out of syringe. Insert syringe tip into bottle opening.



STEP 4. Flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.

STEP 5. Pull yellow part of syringe until it reaches and stays at the correct dose.



STEP 6. Dispense liquid slowly into child's mouth.



**Acetaminophen
160 mg per 5 mL**

Pain & Fever

PAIN RELIEVER/FEVER REDUCER

Infants'



Drug Facts

| | |
|---|-----------------------------|
| Active ingredient (in each 5 mL) | Purpose |
| Acetaminophen 160 mg..... | Pain reliever/fever reducer |

Uses temporarily:

| | |
|--|-------------------|
| ■ reduces fever | ■ the common cold |
| ■ relieves minor aches and pains due to: | ■ flu |
| ■ headache | ■ sore throat |
| ■ toothache | |

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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 has ever had an allergic reaction to this product or any of its ingredients

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

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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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- push air out of syringe. Insert syringe tip into bottle opening

Drug Facts (continued)

- pull yellow part of syringe until it reaches and stays at the correct dose
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Other information

- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105



yourplusguarantee.

If you are not 100% satisfied with this product,

■ push an out of syringe. Insert syringe up into bottle opening.
 ■ flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.

simply return it with your VIC card for a full refund.
 Plus we will replace it with a like item of your choice.
 For full details: 1-800-432-6111 or harristeeter.com.



LOT NO.

EXP.

: 16116 HT CL

HARRIS TEETER INFANTS PAIN AND FEVER

acetaminophen suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69256-161 |
| 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 |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| BUTYLPARABEN (UNII: 3QP11U3FV8) | |
| CALCIUM SULFATE (UNII: WAT0DDB505) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X) | |

Product Characteristics

| | | | |
|-----------------|-----|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69256-161-16 | 1 in 1 CARTON | 11/21/2015 | |
| 1 | | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 11/21/2015 | |

Labeler - Harris Teeter, LLC (048463103)

Revised: 12/2018

Harris Teeter, LLC