

# **CHILDRENS PAIN AND FEVER- acetaminophen 160mg/5ml solution**

## **Calmco LLC**

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**DrKids Children's Pain and Fever**

### **DRUG FACTS**

#### ***Active Ingredient (in each 5mL)***

Acetaminophen, 160mg

#### ***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 for this product • 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 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 or pharmacist before use if**

your child is taking the blood thinning drug warfarin

**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**

In 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.**

- do not give more than directed (see overdose warning)
- use the chart below to confirm dose. If possible, use weight to confirm, otherwise use age
- give the recommended number of vials below following the instructions under "Easy to Use" on the side panel.
- empty each Single-Use Vial required of all liquid when dosing
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

**Dosing Chart**

<b>Weight (lbs)</b>	<b>Age (Years)</b>	<b>Dose (mL)</b>
under 24 lbs	under 2 years	Talk to a doctor
24 -35 lbs	2 - 3 years	1 Single-Use Vial (5 mL)
36 - 47 lbs	4-5 years	Talk to a doctor
48 - 71 lbs	6-10 years	2 Single-Use Vial (10 mL)
72 - 95 lbs	11 years	3 Single-Use Vial (15 mL)

**Other information**

- each Single-Use vial contains 8mg of sodium
- store at 68-77°F (20-25°C)
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken

## Inactive ingredients

citric acid, cherry flavor, edetate disodium, glycerin, maltitol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

## Questions or Comments?

+1 941-202-3270 or visit [www.DrKids.com](http://www.DrKids.com)

## Package

## Package

**Drug Facts** (continued)

**Directions**

- This product does not contain directions or complete warnings for adult use.
- do not give more than directed dose (see overdose warning).
- use the chart below to confirm dose. If possible, use weight to confirm, otherwise use age.
- give the recommended number of vials below following the instructions under "Easy to Use" on the side panel.
- empty each Single-Use Vial required of all liquid when dosing.
- if needed, repeat dose every 4 hours while symptoms last.
- do not give more than 5 times in 24 hours.
- do not give for more than 5 days unless directed by a doctor.

**Dosing Chart**

Weight (lbs)	Age (Years)	Dose (mL)
under 24 lbs.	under 2 years	Talk to a doctor
24-35 lbs.	2-3 years	1 single use vial (5 mL)
36-47 lbs.	4-5 years	Talk to a doctor
48-71 lbs.	6-10 years	2 single use vials (10 mL)
72-95 lbs.	11 years	3 single use vials (15 mL)

**Other Information**

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- Tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.

**Inactive Ingredients**

citric acid, cherry flavor, edetate disodium, glycerin, maltitol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum.

**Questions or Comments?**

941-202-3270 or visit [www.DrKids.com](http://www.DrKids.com)

**Made in the USA:**

Distributed by CalmCo LLC  
Sarasota FL 34240

**WARNING**

CHOKING HAZARD  
Small parts. Keep out of reach of children

**CalmCo.**

Pre-Measured Single-Use Vials  
**20**  
0.17 fl.oz (5 mL) Each  
3.4 fl.oz (100 mL) Total

**Free From:**

- ✓ Alcohol
- ✓ Dyes
- ✓ Sugar

**CHERRY FLAVOR**

**DrKids.com**  
  
  
**@DrKids**

**DrKids®**  
Children's  
**Pain + Fever**  
Acetaminophen  
160 mg / 5 mL

- Relieves pain
- Reduces fevers
- Soothes aches
- Pre-measured dose

**Easy to Use**

- 1 Tap the vial to eliminate air bubbles
- 2 Twist the top of the vial off
- 3 Squeeze the liquid into child's mouth

**Why DrKids:**

Meet DrKids, the safe, clean medicine in a single-use dose. We are parents, too, and our revolutionary vials remove the guesswork of over or under dosing. DrKids is hygienic (so no more sticky cups or syringes) and portable, making it safe and easy to administer wherever you are. DrKids is ready so you can be ready at home or on-the-go. Go forth and conquer!

**Free from:**

- Alcohol
- Dyes
- Ibuprofen & Aspirin
- Sugar

**Drug Facts**

**Keep Outer Package for Complete Product Information**

**Active Ingredient** (in each 5 mL)

Acetaminophen, 160 mg.....Pain reliever/fever reducer

**Purpose**

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
- hives
- 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 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 or pharmacist before use if your child is taking the blood thinning drug warfarin.**

**Stop use and ask doctor if:**

- Pain gets worse or last more than 5 days.
- Fever gets worse or last 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.** In 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.

**Drug Facts Continued to Side Panel**

## Package - 4ct



## CHILDRENS PAIN AND FEVER

acetaminophen 160mg/5ml solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73282-0011
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>MALTITOL</b> (UNII: D65DG142VK)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3Z D4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-0011-1	20 in 1 CARTON	08/06/2021	
1		5 mL in 1 VIAL; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		08/06/2021	

CHILDRENS PAIN AND FEVER

acetaminophen 160mg/5ml solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73282-0115

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

WATER (UNII: 059QF0KO0R)

SORBITOL (UNII: 506T60A25R)

EDETATE DISODIUM (UNII: 7FLD91C86K)

SODIUM METABISULFITE (UNII: 4VON5FNS3C)

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)

GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

MALTITOL (UNII: D65DG142WK)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SODIUM BENZOATE (UNII: OJ245FE5EU)

<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)				
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:73282-0115-4	4 in 1 CARTON	01/11/2022	
<b>1</b>		5 mL in 1 VIAL; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M013		08/06/2021	

**Labeler -** Calmco LLC (079308308)