

CHILDRENS PAIN AND FEVER- acetaminophen 160mg/5ml solution CalmCo 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.

DrKids Children's Pain and Fever

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

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.

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.

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

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

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 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

Package- 20ct Pouch



Single
Use
Vials




Dr Kids[®]

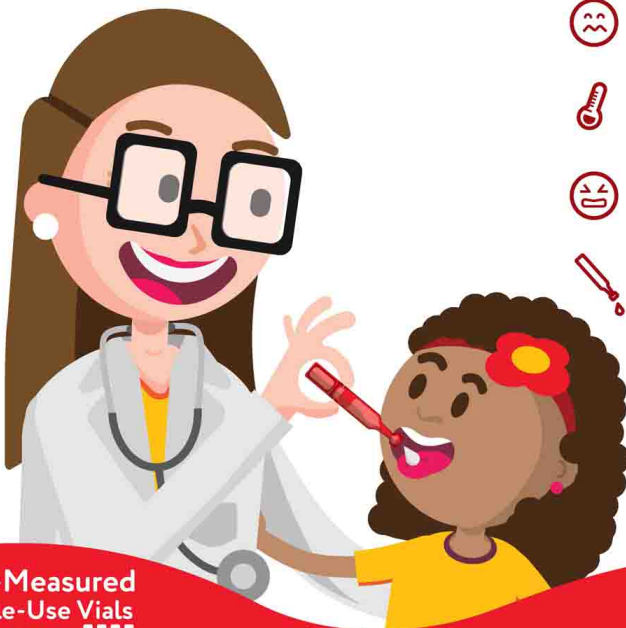
Children's





Pain + Fever


Acetaminophen 160 mg / 5 mL

**Ages 2-11
years**






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



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**



DKPF-UC20-001-03



CHOKING HAZARD
Small parts. Keep out
of reach of children

Made in the USA: Distributed by CalmCo LLC, Sarasota FL 34240

Questions or Comments? 941-202-3270 or visit www.DrKids.com

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

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 or carton is open. Do not use if any vials are open or broken.

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

Dosing Chart

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

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

Drug Facts (continued)
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

These could be signs of a serious condition.
■ New symptoms occur. ■ Redness or swelling is present.
■ Pain gets worse or last more than 5 days. ■ Fever gets worse or last more than 3 days.

Stop use and ask doctor if:
wartin.

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

Ask a doctor before use if your child has liver disease.

Do not use
■ If your child is allergic to acetaminophen or any of the inactive ingredients in this product.
■ You are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. If you are not sure whether a drug contains acetaminophen (prescription or nonprescription), it

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.

Uses Temporarily: ■ Reduces fever
■ Relieves minor aches and pains due to: ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache.

Active Ingredient
Acetaminophen, 160 mg (in each 5 mL)

Purpose
Pain reliever/fever reducer

Drug Facts
Keep Outer Package for Complete Product Information

Easy to Use

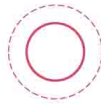
1 Tap the vial to eliminate air bubbles



2 Twist the top of the vial off

3 Squeeze the liquid into child's mouth





CHILDRENS PAIN AND FEVER

acetaminophen 160mg/5ml solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73282-0160(NDC:70302-126)
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MALTITOL (UNII: D65DG142WK)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-0160-1	20 in 1 POUCH	08/05/2022	05/31/2024
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/05/2022	05/31/2024

Labeler - CalmCo LLC (079308308)

Establishment

Name	Address	ID/FEI	Business Operations
CalmCo LLC		079308308	repack(73282-0160)

Revised: 7/2022

CalmCo LLC