

DRKIDS CHILDRENS PAIN AND FEVER- acetaminophen 80mg/piece bar, chewable
CalmCo LLC

DrKids Children's Pain and Fever (USP)

Drug Facts

Active ingredient and Purpose

<i>Active Ingredient (in each piece)</i>	<i>Purpose</i>
Acetaminophen 80mg	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

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.

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 for adults as well as for children even if you do not notice any signs or symptoms.

Other Information

- **each piece contains:** sodium 6 mg. **low sodium**
- store in a cool dry place between 20-25°C (68-77°F).
- **Child Resistant Container;** do not use if printed seal under cap is broken or missing.

Inactive Ingredients

ammonium glycyrrhizate, flavors, geleol mono and diglycerides, glucode syrup, maltitol solution, maltodextrin, neotame, polyethylene glycol 400, povidone K30, propylene glycol, purified water, seaweed extract (carrageenan), sodium chloride, starch, sucralose, sucrose, trisodium citrate dihydrate.

Questions or comments?

Call 1-941-202-3270

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see overdose warning)**
- find right dose on the chart below. If possible, use weight to dose; otherwise, use

age

- **choking hazard:** instruct child to chew each piece thoroughly before swallowing
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Dosing Chart

Weight (lbs)	Age (Years)	Dose (per piece)*
under 24	under 2 years	ask a doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

*or as directed by a doctor

Principal Display Panel

Gummy Bite **DrKids**® Ages 2-11 years
Children's Pain + Fever TRAVEL APPROVED
Acetaminophen 80 mg / Piece

Relieves pain
Reduces fevers
Soothes aches

ORANGE VANILLA FLAVOR 24 Pieces
Free From:
✓ Allergens
✓ Parabens
✓ Alcohol
✓ Dyes

Drug Facts

Active ingredient (in each piece)
Acetaminophen 80 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
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

Drug Facts Continued On Reverse Side

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

PFSC-L-001-01
51505964

3 13992 00066 9

Peel Here

Drug Facts (Continued)

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.

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Questions or comments?

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STOP PEELING



DRKIDS CHILDRENS PAIN AND FEVER

acetaminophen 80mg/piece bar, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73282-2480

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
MALTITOL (UNII: D65DG142WK)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
NEOTAME (UNII: VJ597D52EX)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SUCROSE (UNII: C151H8M554)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CORN SYRUP (UNII: 9G5L16BK6N)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
POVIDONE K30 (UNII: U725QWY32X)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color	white (opaque, beige)	Score	score with uneven pieces
Shape	RECTANGLE	Size	15mm
Flavor	ORANGE (Orange Vanilla Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-2480-1	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2023	

