

PAIN RELIEF FEVER REDUCER CHILDREN- acetaminophen suspension
Ellywell, LLC

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

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.

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 non-prescription). 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 dosage (see overdose warning)

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.</html>

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 take more than directed (see overdose warning)**
- **shake well before using**
- mL= milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- find the right dose on chart below. If possible, use weight to dose, use age.

Weight (lb)	Age (year)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 ml
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 5 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

disodium EDTA, disodium phosphate heptahydrate, flavors, glycerin, methylparaben, monobasic sodium phosphate monohydrate, purified water, sodium metabisulfite, sorbitol solution, stevia, xanthan gum

Questions or Comments?

Call **312-546-1905** M-F/ 9am-5pm / CST

Principal Display Panel

Ellywell

Children's Pain Reliever & Fever Reducer

acetaminophen 160 mg per 5 mL

oral suspension

- orange flavor
- sweetener with stevia
- dye-free
- aspirin and ibuprofen free
- alcohol-free
- for ages 2-11 years

**compare to the active ingredient in Children's Tylenol® Oral Suspension

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER THE CAP IS BROKEN OR MISSING

Distributed by: Ellywell Naperville, IL

Product Label

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

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Distributed by: Elywell Naperville, IL

NDC 80272-002-04

ellywell

Children's Pain Reliever & Fever Reducer

acetaminophen 160 mg per 5 mL oral suspension



- orange flavor
- sweetened with Stevia
- dye-free
- aspirin and ibuprofen free
- alcohol-free
- for ages 2-11 years

**compare to the active ingredient in Children's Tylenol® Oral Suspension




4 fl oz (118 mL)



3 49580 00204 3

PLD-A715A FC007371


Lot No:
Exp. Date:



Since small children are especially vulnerable to the negative impacts of artificial ingredients and high sugar when they are ill, it is important to give them highest quality medicine to help them feel better.

— Mother and Family Medicine Physician, Dr. Dina Pavilonis

Dr. Pavilonis was inspired to create ellywell after noticing the high amount of sugar and unwanted ingredients like artificial sweeteners, flavors, dyes, preservatives in the over-the-counter children's products.



ELLYWELL Children's Pain Reliever & Fever Reducer

PAIN RELIEF FEVER REDUCER CHILDREN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80272-002
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
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEVIA LEAF (UNII: 6TC6NN0876)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80272-002-04	1 in 1 BOX	09/30/2020	
1		118 mL in 1 BOTTLE, PLASTIC; 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	09/30/2020	

Labeler - Ellywell, LLC (117625596)

Revised: 10/2023

Ellywell, LLC