PAIN AND FEVER CHILDRENS- acetaminophen suspension P & L Development, 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

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 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

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.

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 2 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

acesulfame potassium, citric acid, butylparaben, carboxymethylcellulose sodium, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or Comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

**Compare to active ingredients in Children's Tylenol® Oral Suspension

children's

pain relief

Acetaminophen 160 mg per 5 mL

oral suspension

Pain Reliever/Fever Reducer

alcohol free

aspirin free

ibuprofen free

for ages 2-11 years

cherry flavor

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 PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Manufactured by:

PL Developments

Product Label



Drug Facts (continued)

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.

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
or complete warnings for adult use ■ do not take more than directed (see Overdose warning) ■ mL = milliliter
■ shake well before using ■ 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 times in 24 hours ■ find the right dose on chart. If possible, use weight to dose; otherwise, use age.

Drug Facts (continued)

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Questions or comments?

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READYinCASE Children's Pain Relief Cherry Flavor

PAIN AND FEVER CHILDRENS

acetaminophen suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49580-0282 Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (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:49580- 0282-4	1 in 1 BOX	05/31/2016	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49580- 0282-2	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
3	NDC:49580- 0282-8	1 in 1 BOX	05/31/2016	
3		237 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	05/31/2016		

Revised: 2/2024 P & L Development, LLC