

## **DYE FREE PAIN AND FEVER CHILDRENS- acetaminophen suspension QUALITY CHOICE (Chain Drug Marketing Association)**

*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.*

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### **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 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.

**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; otherwise, 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**

- store between 20-25 °C (68-77°F)
- do not refrigerate
- see bottom panel for lot number and expiration date

### **Inactive ingredients**

butylparaben, carboxymethylcellulose sodium, citric acid, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### **Questions or comments?**

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

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

Dye-Free

Infants' Pain Relief

Oral Suspension

Acetaminophen 160 mg per 5 mL

Pain Reliever / Fever Reducer

Alcohol Free

Aspirin Free

Ibuprofen Free

For Ages 2-3 Years

Cherry Flavor

FL OZ (mL)

Use ONLY enclosed dosage cup

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

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare,

distributor of Infants' Tylenol® Oral Suspension.




Distributed by C.D.M.A., ©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

**Package label**

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.</li> <li>if needed, repeat dose every 4 hours while symptoms last</li> <li>do not give more than 5 times in 24 hours</li> <li>do not give more than 5 days unless directed by a doctor</li> <li>find the right dose on chart below. 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If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if your child is allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul> <p><b>Ask a doctor before use if your child has liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.</b></p> <p><b>When using this product, do not exceed recommended dose (see Overdose warning).</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>new symptoms occur</li> <li>redness or swelling is present</li> <li>pain gets worse or lasts more than 5 days</li> <li>fever gets worse or lasts more than 3 days</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> Taking more than the recommended dose (overdose) may cause liver damage. 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<p><b>100% SATISFACTION GUARANTEED</b></p> <p>Distributed by C.D.M.A., Inc. © 43157 W. Nine Mile Novi, MI 48376-0995 www.qualitychoice.com Questions: 248-449-9300</p>																												
<p>PLD-82330 F0003621</p>  <p>6 35515 95289 8</p>																												

**QUALITY CHOICE Children's Pain Relief**

**DYE FREE PAIN AND FEVER CHILDRENS**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-129
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-129-04	1 in 1 BOX	02/29/2016	02/28/2025
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	02/29/2016	02/28/2025

Revised: 4/2023

QUALITY CHOICE (Chain Drug Marketing Association)