

## **INFANTS PAIN AND FEVER- acetaminophen suspension WALGREEN COMPANY**

*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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### **Walgreen Dye-Free Infants' Pain + Fever Drug Facts**

#### **Drug Facts**

#### **Active ingredient (in each 5 mL)**

Acetaminophen 160 mg

#### **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
- 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.

### **Directions**

- **this product does not contain directions or complete warnings for adult use.**
- **do not give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening
- flip bottle upside down. Pull yellow part of syringe to correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

- replace cap tightly to maintain child resistance

### Dosing Chart

Weight (lb)	Age (yr)	Dose (mL) **
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL

**Attention:** use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

### Other information

- store at room temperature
- **Each 5 mL contains:** sodium 2 mg

### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, sodium benzoate, purified water, sodium citrate dihydrate, sorbitol liquid, sucralose, xanthan gum

### Questions?

**1-866-467-2748**

### PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Dye-Free Infants' Tylenol® Oral Suspension\*

NDC 0363-6002-02

Dye-Free

**Infants'  
Pain + Fever**

**Acetaminophen**

Oral Suspension  
Pain Reliever-Fever Reducer

**Free Of:**

- Dyes
- Sugar Free
- Ibuprofen
- Aspirin

- Parabens
- High Fructose Corn Syrup

## Natural Cherry Flavor

No Added Alcohol

Use Only Enclosed Syringe

2 FL OZ ( 60 mL)  
160 mg per 5 mL\*\*\*

\*\*\*Same as Children's TYLENOL

\*This Product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of the registered trademark Dye-Free Infants' Tylenol® Oral Suspension.

**Drug Facts**

**Active ingredient (in each 5 mL)**      **Purpose**  
Acetaminophen 160 mg      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 ■ 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 at 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.  
**Directions ■** this product does not contain directions or complete warnings for adult use. ■ do not give more than directed (see overdose warning) ■ shake well before using ■ mL = milliliter ■ find right dose on chart. If possible, use weight to dose; otherwise, use age. ■ push air out of syringe. Insert syringe tip into bottle opening ■ flip bottle upside down. Pull yellow part of syringe to correct dose ■ dispense liquid slowly into child's mouth, toward inner cheek ■ repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours ■ replace cap tightly to maintain child resistance

Weight (lb)	Age (yr)	Dose (mL)**
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL

\*\* or as directed by a doctor

**Drug Facts (continued)**

**Attention:** use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

**Other information**  
■ each 5 mL contains: sodium 2 mg  
■ 35% at room temperature.

**Inactive ingredients:** anhydrous citric acid, carboxymethylcellulose sodium, glycerin, flavor, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol liquid, sucralose, xanthan gum.


**Questions? 1-866-467-2748**

**TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING.**

\* This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of the registered trademark Dye-Free Infants' Tylenol® Oral Suspension.

**IMPORTANT:**  
Keep this carton for future reference on full labeling.

Distributed by:



0 00000 00000 0

**Dye-Free Infants' Pain + Fever**  
Acetaminophen Oral Suspension

Compare to the active ingredient in Dye-Free Infants' Tylenol® Oral Suspension\*

NDC 0363-6002-02

**Dye-Free Infants' Pain + Fever**  
Acetaminophen Oral Suspension  
Pain Reliever-Fever Reducer

Free Of:

- Dyes
- Parabens
- Sugar Free
- High Fructose Corn Syrup
- Ibuprofen
- Aspirin

**Natural Cherry Flavor**

No Added Alcohol  
Use Only Enclosed Syringe  
2 FL OZ (60 mL)  
160 mg per 5 mL\*\*\*

\*\*\*Same as Children's TYLENOL

**Dye-Free Infants' Pain + Fever**  
Acetaminophen Oral Suspension  
Pain Reliever-Fever Reducer

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Free Of:

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**Natural Cherry Flavor**

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Use Only Enclosed Syringe  
2 FL OZ (60 mL)  
160 mg per 5 mL\*\*\*

\*\*\*Same as Children's TYLENOL

602DFCH02XXXXFC

Lot: \_\_\_\_\_

Exp: \_\_\_\_\_

# INFANTS PAIN AND FEVER

acetaminophen suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-6002
<b>Route of Administration</b>	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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C00X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	white (Dye Free)	<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:0363-6002-02	1 in 1 CARTON	10/10/2022	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/10/2022	

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**Labeler** - WALGREEN COMPANY (008965063)

Revised: 10/2022

WALGREEN COMPANY