

**CHILDRENS TYLENOL- acetaminophen suspension**  
**Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

*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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**Children's TYLENOL<sup>®</sup>**

***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 below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and pour your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

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

\* or as directed by a doctor

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

**Other information**

- each 5 mL contains: **sodium 2 mg**
- store between 20-25°C (68-77°F)
- **do not use if carton tape or bottle wrap imprinted with "TYLENOL" is broken or missing**

**Inactive ingredients**

anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

**Questions or comments?**

call **1-800-458-1635** (toll-free) or **215-273-8755** (collect)

**PRINCIPAL DISPLAY PANEL**

NDC 50580-579-02

Children's  
TYLENOL®

Acetaminophen (160 mg per 5 mL)

Oral Suspension

Pain Reliever-Fever Reducer

Pain+Fever

Ages 2-11 Years

For In-Patient Use Only

Hospital/Government

Not For Retail Sale

Alcohol Free

Ibuprofen Free

Aspirin Free

No Parabens

4 fl oz (120 mL)

160 mg per 5 mL

Grape

Flavor



How can we help?  
**1-800-458-1635**

**FOR IN-PATIENT USE ONLY**  
Hospital/Government  
Not For Retail Sale

**Drug Facts**

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**Drug Facts (continued)**

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**Questions or comments?**

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Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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NDC 50580-579-02

**Children's**  
**TYLENOL**

Acetaminophen (160 mg per 5 mL)  
Oral Suspension  
Pain Reliever-Fever Reducer

**Pain+Fever**  
**Ages 2-11 Years**

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Hospital/Government  
Not For Retail Sale

- Alcohol Free
- Ibuprofen Free
- Aspirin Free
- No Parabens

4 fl oz (120 mL)  
160 mg per 5 mL

**Grape**  
Flavor



**Children's**  
**TYLENOL**

**Pediatricians recommend**  
**TYLENOL<sup>®</sup> for pain and fever**

**Relied on by moms for over 60 years**

**DIRECTIONS:**

**STEP 1.** Shake well before using



**STEP 2.** Remove child protective cap



**STEP 3.** Pour your child's dose into the dosing cup



**IMPORTANT:**

Please see dosing chart or ask a doctor for your child's correct dose

**CHILDRENS TYLENOL**

acetaminophen suspension

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50580-579

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
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
glycerin (UNII: PDC6A3C0OX)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
water (UNII: 059QF0K00R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol solution (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	
xanthan gum (UNII: TTV12P4NEE)	

### Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-579-02	1 in 1 CARTON	01/16/2017	
1		120 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	01/16/2017	

**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)