

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.

Children's TYLENOL®

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

Weight (lb)	Age (yr)	Dose (mL)*
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 imprinted "TYLENOL" or bottle wrap imprinted "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

Ibuprofen Free

Alcohol Free

Aspirin Free

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

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Drug Facts (continued)

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NDC 50580-579-02

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Oral Suspension
Pain Reliever-Fever Reducer

Pain + Fever

Ages 2-11 Years

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Hospital/Government
Not For Retail Sale

Ibuprofen Free
Alcohol Free
Aspirin Free

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

Grape
Flavor



Children's TYLENOL

Pediatricians recommend TYLENOL® 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: 059QF0KO0R)				
sodium benzoate (UNII: OJ245FE5EU)				
sorbitol (UNII: 506T60A25R)				
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)