

## **CHILDRENS TYLENOL- acetaminophen**

**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**

### **Childrens Tylenol**

#### ***Drug Facts***

#### **Active ingredient (in each tablet)**

Acetaminophen 160 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

- temporarily relieves minor aches and pains due to:
  - the common cold
  - flu
  - headache
  - sore throat
  - toothache
- temporarily reduces fever

#### **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)**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew tablets completely before swallowing; do not swallow tablets whole
- 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 (tablets)*</b>
under 24	under 2 years	ask a doctor
24-35	2-3 years	1 tablet
36-47	4-5 years	1½ tablets
48-59	6-8 years	2 tablets
60-71	9-10 years	2½ tablets
72-95	11 years	3 tablets

\* or as directed by a doctor

**Other information**

- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if neck band or foil inner seal imprinted with "TYLENOL" is broken or missing**

**Inactive ingredients**

anhydrous citric acid, cellulose acetate, crospovidone, D&C red no. 7 calcium lake, D&C red no. 30 aluminum lake, dextrose, FD&C blue no. 1 aluminum lake, flavor, magnesium stearate, povidone, sucralose

**Questions or comments?**

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

## Childrens 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**

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- with other drugs containing acetaminophen

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- 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)**

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- fever gets worse or lasts more than 3 days
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### 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 squeeze 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 50580-460-01

**Children's  
TYLENOL®**

**Acetaminophen** (160 mg per 5 mL)  
**Oral Suspension**

**Pain Reliever-Fever Reducer**

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

Ibuprofen Free

Alcohol Free

Aspirin Free

4 fl oz (120 mL)

160 mg per 5 mL

***Grape***

*Flavor*

**BE READY**

**AT HOME**

**OR**

**ON-THE-GO**

Use products only as directed.

NDC 50580-460-01

New Strength & Directions

**Children's  
TYLENOL®**

**Acetaminophen**

Pain Reliever

Fever Reducer

***Pain+Fever***

***Ages 2-11***

***Chewables***

Ibuprofen Free, Aspirin Free

Now

160 mg

Per Tablet

**24**

Chewable

Tablets

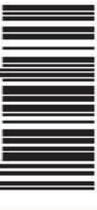
Actual Size

160 mg each

***Grape Flavor***



45-0518-248



LOT  
EXP

1. Contains acetaminophen (160 mg per 5 mL) oral suspension. Do not take with other acetaminophen products. See package insert for full prescribing information.

2. For information on Tylenol, visit [www.tylenol.com](http://www.tylenol.com).

3. © 2017 Johnson & Johnson Consumer Inc. All rights reserved.

4. NDC 50580-522-24

5. Do not exceed recommended dose (see over-the-counter label for more information).

6. Do not take if you are allergic to acetaminophen or any of the other ingredients.

7. Do not take if you have liver disease or if you have ever had liver problems.

8. Do not take if you are taking other medicines that contain acetaminophen.

9. Do not take if you are taking other medicines that contain aspirin.

10. Do not take if you are taking other medicines that contain ibuprofen.

11. Do not take if you are taking other medicines that contain naproxen.

12. Do not take if you are taking other medicines that contain roxicofen.

13. Do not take if you are taking other medicines that contain tramadol.

14. Do not take if you are taking other medicines that contain valproic acid.

15. Do not take if you are taking other medicines that contain zalcitabine.

16. Do not take if you are taking other medicines that contain zidovudine.

17. Do not take if you are taking other medicines that contain zalcitabine.

18. Do not take if you are taking other medicines that contain zalcitabine.

19. Do not take if you are taking other medicines that contain zalcitabine.

20. Do not take if you are taking other medicines that contain zalcitabine.

21. Do not take if you are taking other medicines that contain zalcitabine.

22. Do not take if you are taking other medicines that contain zalcitabine.

23. Do not take if you are taking other medicines that contain zalcitabine.

24. Do not take if you are taking other medicines that contain zalcitabine.



SNAP THIS CODE OR TEXT TYKID TO 87715

MSG & DATA RATES MAY APPLY. TEXT HELP FOR HELP. TEXT STOP FOR STOP.



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

100026724

30039940

NDC 50580-522-24 Children's New Strength & Directions

**TYLENOL**

Acetaminophen Pain Reliever  
Fever Reducer

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

Ibuprofen Free, Aspirin Free

24 Chewable Tablets  
160 mg each

Now  
160 mg  
Per Tablet

Actual Size

Grape Flavor



SNAP THIS CODE OR TEXT TYKID TO 87715

MSG & DATA RATES MAY APPLY. TEXT HELP FOR HELP. TEXT STOP FOR STOP.



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

NDC 50580-612-01

Children's  
**TYLENOL**

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

Pain + Fever  
Ages 2-11 Years

Children's  
**TYLENOL**

Pediatricians recommend TYLENOL® for pain and fever

Relied on by moms for over 60 years

DIRECTIONS:  
STEP 1.



Ibuprofen Free  
Alcohol Free  
Aspirin Free

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

**Grape**  
Flavor



Shake well before using



**STEP 2.**  
Remove child protective cap



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



**IMPORTANT:**

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

**Drug Facts**

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

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

**Drug Facts (continued)**

**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 squeeze 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

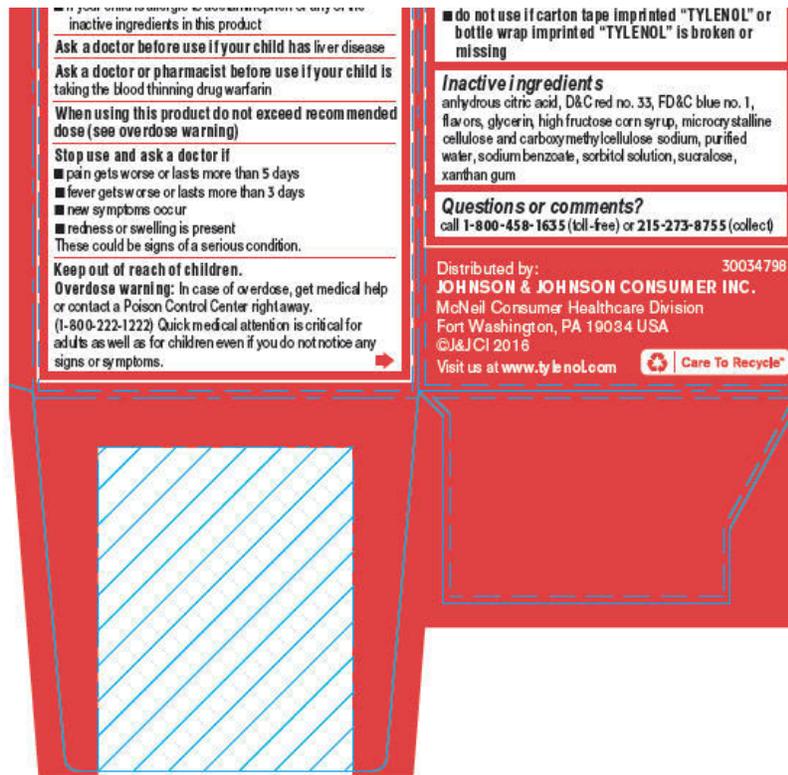
Weight (lb)	Age (yr)	Dose (mL) *
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

\* 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)



## CHILDRENS TYLENOL

acetaminophen kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-460
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-460-01	1 in 1 PACKAGE	05/07/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	24
Part 2	1 BOTTLE	120 mL

## Part 1 of 2

## CHILDRENS TYLENOL

acetaminophen tablet, chewable

### Product Information

Item Code (Source)	NDC:50580-522
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<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
cellulose acetate (UNII: 3J2P07GVB6)	
crospovidone (UNII: 2S7830E561)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 30 (UNII: 2S42T2808B)	
aluminum oxide (UNII: LM26O6933)	
dextrose, unspecified form (UNII: IY9XDZ35W2)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
magnesium stearate (UNII: 70097M6B0)	
povidone, unspecified (UNII: FZ989GH94E)	
sucralose (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	TY;160;HALF;HALF
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-522-24	1 in 1 CARTON		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	02/27/2017	

### Part 2 of 2

**CHILDRENS TYLENOL**  
acetaminophen suspension

**Product Information**

<b>Item Code (Source)</b>	NDC:50580-612
<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>
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**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-612-01	1 in 1 CARTON		
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

**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	08/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/07/2018	

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

Revised: 12/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division