

**CHILDRENS TYLENOL- acetaminophen**  
**Johnson & Johnson Consumer Inc.**

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**Children's Tylenol**

**Childrens Tylenol**

***Drug Facts***

**Active ingredient (in each chewable 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)**
- **chew or crush tablets completely before swallowing; do not swallow tablets whole**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- 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 lbs	2-3 years	1 tablet
36-47 lbs	4-5 years	1½ tablets
48-59 lbs	6-8 years	2 tablets
60-71 lbs	9-10 years	2½ tablets
72-95 lbs	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

#### Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes

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- 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)**

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- fever gets worse or lasts more than 3 days
- new symptoms occur
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These could be signs of a serious condition.

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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

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL) *</b>
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	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 is opened. Do not use if 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 50580-460-01

**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

No Parabens

**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

***Children's***  
***TYLENOL***®

**Acetaminophen**  
Pain Reliever  
Fever Reducer

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

Chew or crush tablets completely  
before swallowing

Ibuprofen Free

Aspirin Free

160 mg  
Per Tablet

**24**  
Chewable  
Tablets

Actual Size

**160 mg each**

***Grape*** *Flavor*





How can we help?  
☎ 1-800-458-1635

✓  
Check the ingredients in your medicine  
Use only 1 product  
that contains acetaminophen at a time

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  
No Parabens

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

**Grape  
Flavor**

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
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Fort Washington, PA 19034 USA  
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Pat. [www.jjciipats.com](http://www.jjciipats.com)

MCN-CT-0728

**BE READY**

**AT HOME**



OR



**ON-THE-GO**

Use products only as directed

NDC 50580-460-01

**Children's  
TYLENOL®**

Acetaminophen Pain Reliever  
Fever Reducer

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

Chew or crush tablets completely  
before swallowing

Ibuprofen Free  
Aspirin Free

160 mg  
per Tablet

Actual Size

**24 Chewable  
Tablets**  
**160 mg each**

**Grape Flavor**

3029613



3 00450 29613 9

Important: Read all product information before using.  
Keep this box for important information.

**Drug Facts**

**Active ingredient (in each chewable tablet)** **Purpose**  
Acetaminophen (160 mg) **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 you:  
■ take more than 3 doses in 24 hours, which is the maximum daily amount  
■ take other drugs containing acetaminophen

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness ■ itches ■ rash

If a skin reaction occurs, stop use and seek medical help right away.  
**Stomach warning:** Acetaminophen is safe, but if you take more than 2 days, it is accompanied or followed by liver, headache, rash, nausea, vomiting, consult a doctor promptly.

**Do not use** ■ with any other drug containing acetaminophen (prescription or over-the-counter). 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.**

**Keep this box for important information.**



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



# Ages 2-11 Years

Alcohol Free  
Ibuprofen Free  
Aspirin Free  
No Parabens



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

**Grape**  
Flavor

# For over 60 years

## DIRECTIONS:

**STEP 1.**  
Shake well  
before using



**STEP 2.**  
Remove child  
protective  
cap



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

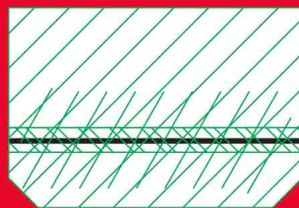


## IMPORTANT:

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



100% OF THE TYLENOL BRAND IS MADE IN THE USA



## Drug Facts

### Active ingredient (in each 5 mL)

Acetaminophen 160 mg..... Pain reliever/fever reducer

### Purpose

### 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

## 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 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	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 is opened. Do not use if bottle wrap imprinted with "TYLENOL" is broken or missing

### Inactive ingredients



## 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
Route of Administration	ORAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
CROSPVIDONE (UNII: 2S7830E561)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

## Product Characteristics

Color	purple	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor	GRAPE	Imprint Code	TY;160;HALF;HALF
Contains			

## 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 Drug	M013	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>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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 Drug	M013	08/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/07/2018	

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 2/2024

Johnson & Johnson Consumer Inc.