### CHILDRENS TYLENOL- acetaminophen Kenvue Brands LLC

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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

Weight (lb)	Age (yr)	Dose (tablets) *
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

<sup>\*</sup> 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

- 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 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

<sup>\*</sup> 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

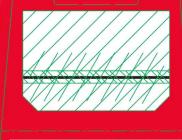












#### Drug Facts

Active ingredient (in each 5 mL)

Purpose

cetaminophen 160 n

#### Uses temporarily:

- reduces fever ■ relieves minor aches and pains due to: ■ headache
- the common cold flu 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

If a skin reaction occurs, stop use and seek medical help

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 aking the blood thinning drug warfari

#### 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

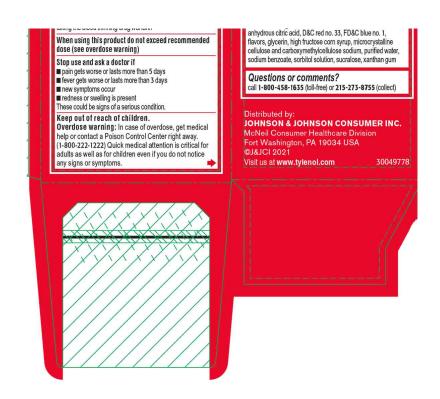
\* or as directed by a doctor

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

#### **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**

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

**Basis of Strength Strength** 

ACETAMINOPHEN

160 mg

Inactive	Ingred	ients

l	Ingredient Name	Strength
ı		

SUCRALOSE (UNII: 96K6UQ3ZD4)

CELLULOSE ACETATE (UNII: 3J2P07GVB6)

CROSPOVIDONE (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** 

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#	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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M013	02/27/2017	

### Part 2 of 2

#### **CHILDRENS TYLENOL**

acetaminophen suspension

### **Product Information**

Item Code (Source) NDC:50580-612

**Route of Administration** ORAL

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 160 mg in 5 mL

**Inactive Ingredients** 

XANTHAN GUM (UNII: TTV12P4NEE)

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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: K6790BS311)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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- 612-01	1 in 1 CARTON		
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 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 - Kenvue Brands LLC (118772437)

Revised: 11/2024 Kenvue Brands LLC