

CHILDRENS TYLENOL- acetaminophen tablet, chewable
Johnson & Johnson Consumer Inc.

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	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 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, dextrose, flavor, magnesium stearate, povidone, sucralose

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-521-24

Children's

TYLENOL ®

Acetaminophen

Pain Reliever

Fever Reducer

Ibuprofen Free

Aspirin Free

Pain+Fever Ages 2-11

Chewables

Chew or crush tablets completely

before swallowing

160 mg

Per Tablet

24 Chewable Tablets

160 mg each

Actual Size

Bubble Gum Flavor

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

Drug Facts

Active ingredient (in each chewable tablet) **Purpose**
 Acetaminophen (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 5 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 ■ hives ■ rash ■ blisters
 If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: 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 or pharmacist 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.

Pediatricians recommend TYLENOL[®] for pain and fever
Caregivers have relied on Children's TYLENOL[®] for over 60 years



Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA
 Pat. www.jjcpatents.com

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Drug Facts (continued)

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 3 days
 ■ fever gets worse or lasts more than 3 days ■ new symptoms occur
 ■ dizziness 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.
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 ■ chew or crush tablets completely before swallowing; do not swallow tablets whole

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

Drug Facts (continued)

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

Inactive ingredients: atropine, citric acid, cellulose acetate croscopolone, D&C color no. 7, calcium phosphate, dextrose, flavin, magnesium stearate, polydioxane succinate

Questions or comments?
 Call 1-800-458-1635 (ask for 215-217-8155) (collect)



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

30054529

62545005

NDC 50580-521-24

Children's TYLENOL[®]

Acetaminophen Pain reliever, Fever reducer

Ibuprofen Free, Aspirin Free

Pain + Fever Chewables Ages 2-11

Chew or crush tablets completely before swallowing

160 mg Per Tablet

24 Chewable Tablets
 160 mg each

Bubble Gum Flavor



CHILDRENS TYLENOL
 acetaminophen tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-521

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		
	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
	CELLULOSE ACETATE (UNII: 3J2P07GVB6)			
	D&C RED NO. 7 (UNII: ECW0LZ41X8)			
	DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
	SUCRALOSE (UNII: 96K6UQ3ZD4)			
	CROSPVIDONE (UNII: 2S7830E561)			
Product Characteristics				
Color	pink	Score	2 pieces	
Shape	ROUND	Size	16mm	
Flavor	BUBBLE GUM	Imprint Code	TY;160;HALF;HALF	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-521-24	1 in 1 CARTON	02/27/2017	
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		

Labeler - Johnson & Johnson Consumer Inc. (878046358)