

CHILDRENS TYLENOL- acetaminophen tablet, chewable
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 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 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)

PRINCIPAL DISPLAY PANEL

NDC 50580-522-24

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

Grape Flavor



CHILDRENS TYLENOL

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	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
CROSPVIDONE (UNII: 2S7830E561)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
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)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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	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 not final	part343	02/27/2017	

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

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