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

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	2 ¹ / ₂ 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, 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 mars as also

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
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Active migre	dient/Active Mo	•		
		ient Name	Basis of Stren	
ACETAMINOPHE	N (UNII: 36209ITL9D)) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg
Inactive Ing	redients			
		Ingredient Name		Strength
CROSPOVIDONE	(UNII: 2S7830E561)			
ANHYDROUS CI	TRIC ACID (UNII: XF4	17D3PSL)		
CELLULOSE ACI	ETATE (UNII: 3J2P07G	SVB6)		
D&C RED NO. 7	(UNII: ECW0LZ41X8)			
	0 (UNII: 2S42T2808B)			
	DE (UNII: LMI2606933			
	SPECIFIED FORM (U			
	. 1 ALUMINUM LAKE			
	EARATE (UNII: 70097			
-	SPECIFIED (UNII: FZ9	89GH94E)		
SUCRALOSE (UN	III: 96K6UQ3ZD4)			
Product Cha	racteristics			
Color	purple	Score	2 pieces	
Shape	ROUND	Size	16mm	
Flavor	GRAPE	Imprint Code	TY;160;HALF;HALF	
Contains				

Packaging							
#	ltem 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 Start	Marketing End			
	Marketing	Application Number or Monograph	Harketing Start	Marketing Life			
	Category	Citation Citation	Date	Date			

Labeler - Johnson & Johnson Consumer Inc. (878046358)