

TYLENOL FOR CHILDREN PLUS ADULTS- acetaminophen suspension
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.

TYLENOL For Children Plus Adults

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
 - muscular aches
 - backache
 - minor pain of arthritis
 - premenstrual and menstrual cramps

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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 you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user 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 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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.

If pregnant or breast-feeding, ask a health professional before use.

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

- **do not give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- **Children 2 years to under 12 years:**
 - find right dose on chart below. If possible, use weight to dose; otherwise, use age.
 - remove the child protective cap and squeeze the dose into the dosing cup
 - repeat dose every 4 hours while symptoms last
 - do not take more than 5 times in 24 hours unless directed by a doctor
 - do not take for more than 5 days unless directed by a doctor

Weight (lb)	Age (years)	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

▪ **Adults and children 12 years and over:**

- take 20 mL (2 × 10 mL) every 4 hours while symptoms last. For adult dosing, the dosing cup needs to be filled to 10 mL line twice.
- do not take more than 5 doses (100 mL) in 24 hours unless directed by a doctor
- do not take for more than 10 days unless 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: **potassium 5 mg**
- store between 20-25°C (68-77°F)
- **do not use if carton tape or bottle wrap imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

anhydrous citric acid, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol solution, sucralose, sucrose, xanthan gum

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-177-08
 Same as Children's TYLENOL
 with adult dosing

TYLENOL®
 FOR CHILDREN
 + ADULTS FAMILY

Acetaminophen (160 mg per 5 mL)
 Oral Suspension

Pain Reliever-Fever Reducer

DYE-FREE

Pain+Fever

Ages 2 Years - Adult

FREE OF:

Dyes

Alcohol

Ibuprofen

Aspirin

Parabens

High Fructose

Corn Syrup

8 fl oz (240 mL)

160 mg per 5 mL

Cherry

Flavor



How can we help?
☎ 1-800-458-1635

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with adult dosing

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Actual Size

- ☑ **TYLENOL® - Doctor Recommended Brand of Pain Reliever**
- ☑ **Clinically proven strong, fast pain relief**

DIRECTIONS:

STEP 1.
Shake well
before using



STEP 2.
Remove child
protective cap



STEP 3.
Squeeze the
dose into the
dosing cup



IMPORTANT:

Please see dosing chart or ask a doctor for the correct dose

8 fl oz (240 mL)
160 mg per 5 mL

Cherry
Flavor



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

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Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- rash

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.

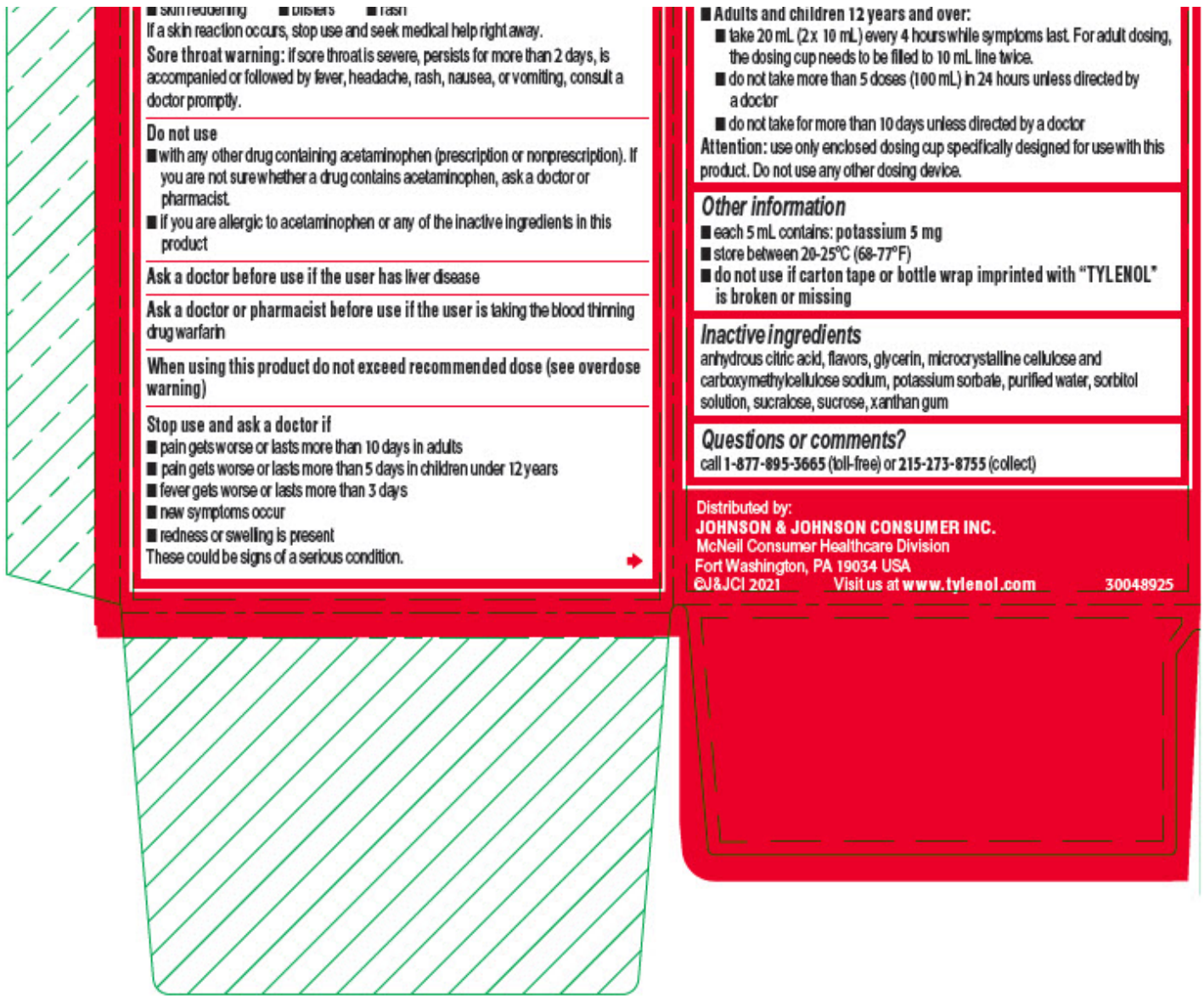
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TYLENOL FOR CHILDREN PLUS ADULTS

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-177
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	

glycerin (UNII: PDC6A3C0OX)	
microcrystalline cellulose (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
potassium sorbate (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
sorbitol solution (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	
sucrose (UNII: C151H8M554)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-177-08	1 in 1 CARTON	07/01/2021	
1		240 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 not final	part343	07/01/2021	

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