# TYLENOL FOR CHILDREN PLUS ADULTS- acetaminophen suspension Johnson & Johnson Consumer Inc.

-----

#### 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	ack a doctor

UIIUCI 24	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

# 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

Aĺcohol

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

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

#### **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



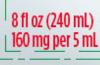
### STEP 3.

Squeeze the dose into the dosing cup



#### IMPORTANT:

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











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

## **Drug Facts**

Active ingredient (in each 5 mL)

Purpose

Pain reliever/fever reducer

#### Uses

- temporarily:
- reduces fever

Acetaminophen 160 mg.

- relieves minor aches and pains due to:
- the common cold
- headache
- toothache
- backache
- flu
- sore throat
- muscular aches minor pain of arthritis
- premenstrual and menstrual cramps

#### Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may

- 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

Allerov alert; acetaminophen may cause severe skin reactions. Symptoms may include:

#### Drug Facts (continued)

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

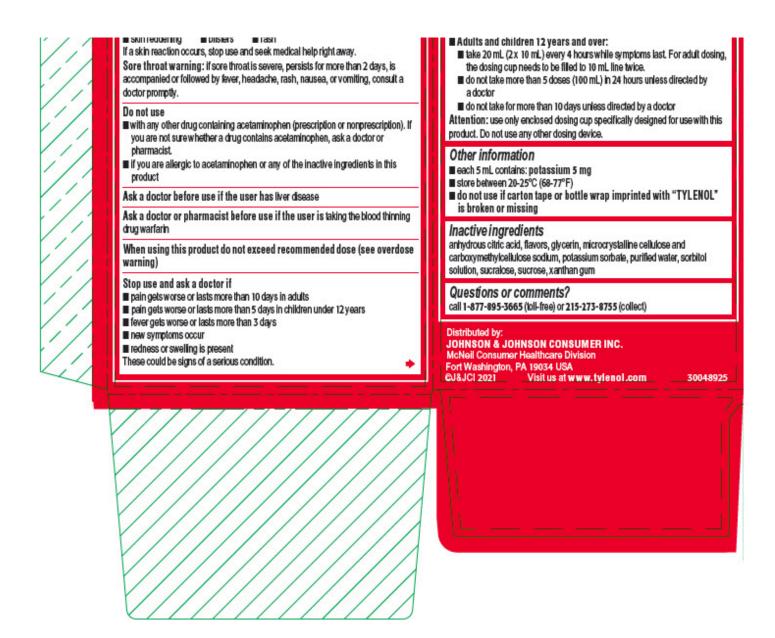
Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### Directions

- do not give more than directed (see overdose warning)
- shake well before using
- mL = millitter
- 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



## 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	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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			

P	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 Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
OTC Monograph Drug	M013	07/01/2021		

# Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.