# CHILDRENS TYLENOL- acetaminophen powder Johnson & Johnson Consumer Inc.

-----

#### Children's TYLENOL

**Drug Facts** 

# Active ingredient (in each powder)

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

# 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)
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- tear packet and pour powder on your child's tongue
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (powder) *
under 48	under 6 years	do not use
48-59 lbs	6-8 years	2 powders
60-71 lbs	9-10 years	2 powders
72-95 lbs	11 years	3 powders

<sup>\*</sup> or as directed by a doctor

#### Other information

store between 20-25°C (68-77°F)

# do not use if packet is torn or damaged

#### **Inactive ingredients**

citric acid, ethylcellulose, flavor, magnesium stearate, maltodextrin, sodium bicarbonate, sucralose, xylitol

# Questions or comments?

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

#### PRINCIPAL DISPLAY PANEL

NDC 50580-555-04

Children's TYLENOL ®

Acetaminophen Pain Reliever-Fever Reducer

Ibuprofen Free Aspirin Free

Pain+Fever Ages 6-11

**DISSOLVE PACKS** 

No Water Needed Dissolves in Seconds Dye - Free

30 Packets\* 160 mg each packet

Wild Berry Flavor

\*Packets of Powder



Children's NDC 50580-555-04 YLENOL

Acetaminophen

Pain Reliever-Fever Reducer

Pain+Fever

Ibuprofen Free Aspirin Free

Ages 6-11

- No Water Needed
- Dissolves in Seconds
- ✓ Dye Free

30 Packets\* 160 mg each packet

Wild Berry Flavor

\*Packets of Powder

Children's YLENOL

**DISSOLVE PACKS** 

- No Water Needed
- **Dissolves in Seconds** ✓ Dye - Free







\$291-857-008-1 ]



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

#### Drug Facts

Active ingredient (in each powder) Purpose

Uses temporarily: ■ reduces fever

■ relieves minor aches and pains due to: ■ flu ■ headache ■ sore throat

■ the common cold ■ toothache

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

#### Drug Facts (continued)

■ 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 adultuse.



**DISSOLVE PACKS** 

Important: See Drug Facts for Complete Product Information



## **CHILDRENS TYLENOL**

acetaminophen powder

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-555

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 160 mg

# Inactive Ingredients Ingredient Name Strength ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B) MAGNESIUM STEARATE (UNII: 70097M6I30) MALTODEXTRIN (UNII: 7CVR7L4A2D) SODIUM BICARBONATE (UNII: 8MDF5V39QO) SUCRALOSE (UNII: 96K6UQ3ZD4) XYLITOL (UNII: VCQ006KQ1E)

#### **Product Characteristics**

Color	white (off white)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:50580-555- 04	30 in 1 CARTON	07/15/2019				
1		1 in 1 PACKET; Type 0: Not a Combination Product					
2	NDC:50580-555- 05	18 in 1 CARTON	07/15/2019				
2		1 in 1 PACKET; 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	07/15/2019			

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

Revised: 1/2024 Johnson & Johnson Consumer Inc.