

## **CHILDRENS TYLENOL- acetaminophen powder**

**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.*

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### **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. 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

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

\* 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 50580-555-05

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

18 Packets\*  
160 mg each packet

Wild Berry

Flavor

\*Packets of Powder

NDC 50580-555-05

# Children's **TYLENOL**<sup>®</sup>

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**Flavor**  
\*Packets of Powder.

**Important: See Drug Facts for Complete Product Information**

### **Directions**

**STEP 1.**

Fold on line and tear



**STEP 2.**

Pour powder on your child's tongue



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How can we help?  
1-800-458-1635



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

**Drug Facts**

**Active ingredient (in each powder) Purpose**  
 Acetaminophen 160 mg..... Pain relief/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.

**Drug Facts (continued)**

■ 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 a liver disease 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.  
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 CONSUMER INC.**  
 McNeil Consumer  
 Healthcare Division  
 Fort Washington, PA 19034  
 USA  
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**Drug Facts (continued)**

■ repeat dose every 4 hours while symptoms last  
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**Drug Facts (continued)**

**Other information** ■ store between 20-25°C (68-77°F)  
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**Inactive ingredients** citric acid, ethylcellulose, flavor, magnesium stearate, mannitol, sodium bicarbonate, sucralose, xylitol

**Questions or comments?**

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**CHILDRENS TYLENOL**

acetaminophen powder

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-555
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg
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### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
ethylcellulose, unspecified (UNII: 7Z8S9VYZ4B)	
magnesium stearate (UNII: 70097M6B0)	
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			

### 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 NOT FINAL	part343	07/15/2019	

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

Revised: 7/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division