

TYLENOL EXTRA STRENGTH- acetaminophen powder
Kenvue Brands LLC

TYLENOL Extra Strength

Drug Facts

Active ingredient (in each powder)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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.

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 you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 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.

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 take more than directed (see overdose warning)**
- tear packet and pour powder directly on tongue

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 2 powders every 6 hours, while symptoms last▪ do not take more than 6 powders in 24 hours, unless directed by a doctor▪ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- each powder contains: **sodium 4 mg**
- 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 **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-209-04

Extra Strength
TYLENOL[®]
FOR ADULTS

Acetaminophen
Pain Reliever-Fever Reducer

DISSOLVE PACKS

- NO WATER NEEDED
- DISSOLVES IN SECONDS

32 Packets*
500 mg
each packet

Berry
Flavor

*Packets of Powder



NDC 50580-209-04

Extra Strength TYLENOL®

Acetaminophen
Pain Reliever-Fever Reducer

FOR ADULTS

DISSOLVE PACKS

- ✓ NO WATER NEEDED
- ✓ DISSOLVES IN SECONDS

32 Packets*
500 mg
each packet



Berry
Flavor
*Packets of Powder

Extra Strength
TYLENOL®
FOR ADULTS

DISSOLVE PACKS

- ✓ NO WATER NEEDED
- ✓ DISSOLVES IN SECONDS

Distributed by:
JOHNSON & JOHNSON
CONSUMER INC.
McNeil Consumer
Healthcare Division
Fort Washington, PA 19034
USA
©J&JCI 2021



How can we help?
1-877-895-3665



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

Drug Facts

Active ingredient (in each powder) **Purpose**
Acetaminophen 500 mg Pain reliever/fever reducer

Uses ■ temporarily relieves minor aches and pains due to:
■ the common cold ■ headache ■ backache
■ minor pain of arthritis ■ toothache ■ muscular aches
■ premenstrual and menstrual cramps
■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
■ more than 4,000 mg of acetaminophen in 24 hours
■ with other drugs containing acetaminophen

Drug Facts (continued)

■ 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 take more than directed** (see overdose warning)
■ tear packet and pour powder directly on tongue
adults ■ take 2 powders every 6 hours, while

Extra Strength
TYLENOL®
FOR ADULTS

DISSOLVE PACKS

Important: See Drug Facts for Complete Product Information



TYLENOL EXTRA STRENGTH

acetaminophen powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-209
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 0.95 g

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	Score	
--------------	-------	--------------	--

Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-209-02	12 in 1 CARTON	06/15/2020	
1		0.95 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50580-209-04	32 in 1 CARTON	06/15/2020	
2		0.95 g 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	06/15/2020	

Labeler - Kenvue Brands LLC (118772437)

Revised: 9/2025

Kenvue Brands LLC