TYLENOL EXTRA STRENGTH- acetaminophen powder
Johnson & Johnson Consumer Inc.

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	▪ 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

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Extra Strength

TYLENOL®

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Pain Reliever-Fever Reducer

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

TYLENOL Extra Strength FOR ADULTS

DISSOLVE PACKS

- NO WATER NEEDED
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How can we help? 1-877-895-3665

HISTORY OF RELIEF • HERITAGE OF CARE • TYLENOL

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

Drug Facts

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Acetaminophen 500 mg ..... Pain reliever/fever reducer

Uses

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- with other drugs containing acetaminophen

Drug Facts (continued)

- new symptoms occur
- redness or swelling is present

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TYLENOL Extra Strength 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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.