

TYLENOL REGULAR STRENGTH- acetaminophen tablet
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.

TYLENOL®
Regular Strength

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children.

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.

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 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 take more than directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 2 tablets every 4 to 6 hours while symptoms last▪ do not take more than 10 tablets in 24 hours, unless directed by a doctor▪ do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	<ul style="list-style-type: none">▪ take 1 tablet every 4 to 6 hours while symptoms last▪ do not take more than 5 tablets in 24 hours▪ do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

- store between 20-25°C (68-77°F)
- **do not use if carton is opened or neck wrap or foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

magnesium stearate, modified starch, powdered cellulose, pregelatinized starch, sodium starch

glycolate

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-496-60

TYLENOL[®]

Acetaminophen

Pain Reliever

Fever Reducer

Regular Strength

Actual Size

100 Tablets

325 mg each

30034974



Drug Facts

Active ingredient (in each tablet) Purpose
Acetaminophen 325 mg.....Pain reliever/fever reducer

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 ■ headache ■ muscular aches
 ■ backache ■ minor pain of arthritis
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 ■ 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 redness ■ hives ■ rash
 ■ skin peeling ■ blisters ■ itchy
 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



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

SNAP THIS CODE OR TEXT TYLENOL TO 87715

MSG & DATA RATES MAY APPLY
 TEXT HELP FOR HELP
 TEXT STOP FOR STOP



30034974

EXP

3 0045-0496-60 7



TYLENOL[®]

Acetaminophen Pain Reliever
 Fever Reducer

Regular Strength



Actual Size
100 Tablets each 325 mg

NDC 50580-496-60

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 Market Consumer Healthcare Division
 Fort Washington, PA 19034 USA C12JC12018 www.tylenol.com

Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Questions or comments?
 pregelatinized starch, sodium starch glycolate

Inactive ingredients
 magnesium stearate, modified starch, powdered cellulose, or missing

Other information
 ■ does not use if certain imprint with "TYLENOL" is broken
 ■ store between 20-25°C (68-77°F)
 ■ see Facts (continued)

Drug Facts (continued)

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 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.
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 ■ do not take more than 5 tablets in 24 hours
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 children under 6 years
 ask a doctor



30034974

TYLENOL REGULAR STRENGTH

acetaminophen tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50580-496

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg

Inactive Ingredients

Ingredient Name	Strength
magnesium stearate (UNII: 70097M6B30)	
powdered cellulose (UNII: SMD1X3XO9M)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TYLENOL;325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-496-60	1 in 1 CARTON	02/01/1999	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-496-98	1 in 1 CARTON	05/31/2019	
2		100 in 1 BOTTLE, PLASTIC; 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	02/01/1999	

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

Revised: 5/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division